RULES
OF
TENNESSEE DEPARTMENT OF HEALTH
BOARD FOR LICENSING HEALTH CARE FACILITIES

CHAPTER 1200-8-1
STANDARDS FOR HOSPITALS

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1200-8-1-.01 DEFINITIONS.

(1) Acceptable Plan of Correction. The Licensing Division shall approve a hospital's acceptable plan to correct deficiencies identified during an on-site survey conducted by the Survey Division or its designated representative. The plan of correction shall be a written document and shall provide, but not limited to, the following information:

(a) How the deficiency will be corrected.

(b) Who will be responsible for correcting the deficiency.

(c) The date the deficiency will be corrected.

(d) How the facility will prevent the same deficiency from re-occurring.

(2) Accredited Record Technician (ART). A person currently accredited as such by the American Medical Records Association.

(3) Adult. An individual who has capacity and is at least 18 years of age.

(4) Advance Directive. An individual instruction or a written statement relating to the subsequent provision of health care for the individual, including, but not limited to, a living will or a durable power of attorney for health care.

(5) Agent. An individual designated in an advance directive for health care to make a health care decision for the individual granting the power.

(6) Board. The Tennessee Board for Licensing Health Care Facilities.

(7) Capacity. An individual's ability to understand the significant benefits, risks, and alternatives to proposed health care and to make and communicate a health care decision. These regulations do not affect the right of a patient to make health care decisions while having the capacity to do so. A patient shall be presumed to have capacity to make a health care decision, to give or revoke an advance directive, and to designate or disqualify a surrogate. Any person who challenges the capacity of a patient shall have the burden of proving lack of capacity.

(Rule 1200-8-1-.01, continued)

(8) Cardiopulmonary Resuscitation (CPR). The administering of any means or device to support cardiopulmonary functions in a patient, whether by mechanical devices, chest compressions, mouth-to-mouth resuscitation, cardiac massage, tracheal intubation, manual or mechanical ventilators or respirations, defibrillation, the administration of drugs and/or chemical agents intended to restore cardiac and/or respiratory functions in a patient where cardiac or respiratory arrest has occurred or is believed to be imminent.

(9) Certified Master Social Worker. A person currently certified as such by the Tennessee Board of Social Worker Certification and Licensure.

(10) Certified Nurse Practitioner. A person who is licensed as a registered nurse and has further been issued a certificate of fitness to prescribe and/or issue legend drugs by the Tennessee Board of Nursing.

(11) Certified Registered Nurse Anesthetist. A registered nurse currently licensed by the Tennessee Board of Nursing who is currently certified as such by the American Association of Nurse Anesthetists.

(12) Certified Respiratory Therapist. A person currently certified as such by the Tennessee Board of Medical Examiners' Council on Respiratory Care.

(13) Certified Respiratory Therapy Technician. A person currently certified as such by the Tennessee Board of Medical Examiners' Council on Respiratory Care.

(14) Clinical Laboratory Improvement Act (CLIA). The federal law requiring that clinical laboratories be approved by the U.S. Department of Health and Human Services, Health Care Financing Administration.

(15) Collaborative Practice. The implementation of the collaborative plan that outlines procedures for consultation and collaboration with other health care professional, e.g., licensed physicians and mid-level practitioners.

(16) Collaborative Plan. The formal written plan between the mid-level practitioners and a licensed physician.

(17) Commissioner. The Commissioner of the Tennessee Department of Health or his or her authorized representative.

(18) Competent. A patient who has capacity.

(19) Corrective Action Plan/Report. A report filed with the department by the facility after reporting an unusual event. The report must consist of the following:

(a) the action(s) implemented to prevent the reoccurrence of the unusual event,

(b) the time frames for the action(s) to be implemented,

(c) the person(s) designated to implement and monitor the action(s), and

(d) the strategies for the measurements of effectiveness to be established.

(20) Critical Access Hospital. A hospital located in a rural area, certified by the Department as being a necessary provider of health care services to residents of the area, which makes available twenty-four (24) hour emergency care; is a designated provider in a rural health network; provides not more than twenty-five (25) acute care inpatient beds for providing inpatient care not to exceed an annual average of ninety-six (96) hours, and has a quality assessment and performance improvement program and

(Rule 1200-8-1-.01, continued)

procedures for utilization review. If swing-bed approval has been granted, all twenty-five (25) beds can be used interchangeably for acute or Skilled Nursing Facility (SNF/swing-bed) level of care services.

(21) Dentist. A person currently licensed as such by the Tennessee Board of Dentistry.

(22) Department. The Tennessee Department of Health.

(23) Designated Physician. A physician designated by an individual or the individual's agent, guardian, or surrogate, to have primary responsibility for the individual's health care or, in the absence of a designation or if the designated physician is not reasonably available, a physician who undertakes such responsibility.

(24) Designation. An official finding and recognition by the Department of Health that an acute care hospital meets Tennessee State Rural Health Care Plan requirements to be a Critical Access Hospital.

(25) Dietitian. A person currently licensed as such by the Tennessee Board of Dietitian/Nutritionist Examiners. Persons exempt from licensure shall be registered with the American Dietetics Association pursuant to T.C.A. §63-25-104.

(26) Do Not Resuscitate (DNR) Order. An order entered by the patient's treating physician in the patient's medical records which states that in the event the patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted. The order may contain limiting language to allow only certain types of cardiopulmonary resuscitation to the exclusion of other types of cardiopulmonary resuscitation.

(27) Electronic Signature. The authentication of a health record document or documentation in an electronic form achieved through electronic entry of an exclusively assigned, unique identification code entered by the author of the documentation.

(28) Emancipated Minor. Any minor who is or has been married or has by court order or otherwise been freed from the care, custody and control of the minor's parents.

(29) Emergency Responder. A paid or volunteer firefighter, law enforcement officer, or other public safety official or volunteer acting within the scope of his or her proper function under law or rendering emergency care at the scene of an emergency.

(30) Graduate Registered Nurse Anesthetist. A registered nurse currently licensed in Tennessee who is a graduate of a nurse anesthesia educational program that is accredited by the American Association of Nurse Anesthetist's Council on Accreditation of Nurse Anesthesia Educational Programs and awaiting initial certification examination results, provided that initial certification is accomplished within eighteen (18) months of completion of an accredited nurse anesthesia educational program.

(31) Guardian. A judicially appointed guardian or conservator having authority to make a health care decision for an individual.

(32) Hazardous Waste. Materials whose handling, use, storage, and disposal are governed by local, state or federal regulations.

(33) Health Care. Any care, treatment, service or procedure to maintain, diagnose, treat, or otherwise affect an individual's physical or mental condition, and includes medical care as defined in T.C.A. § 32-11-103(5).

(34) Health Care Decision. Consent, refusal of consent or withdrawal of consent to health care.

(Rule 1200-8-1-.01, continued)

(35) Health Care Decision-maker. In the case of a patient who lacks capacity, the patient's health care decision-maker is one of the following: the patient's health care agent as specified in an advance directive, the patient's court-appointed guardian or conservator with health care decision-making authority, the patient's surrogate as determined pursuant to Rule 1200-8-1-.13 or T.C.A. §33-3-220, the designated physician pursuant to these Rules or in the case of a minor child, the person having custody or legal guardianship.

(36) Health Care Institution. A health care institution as defined in T.C.A. § 68-11-1602.

(37) Health Care Provider. A person who is licensed, certified or otherwise authorized or permitted by the laws of this state to administer health care in the ordinary course of business or practice of a profession.

(38) Hospital. Any institution, place, building or agency represented and held out to the general public as ready, willing and able to furnish care, accommodations, facilities and equipment for the use, in connection with services of a physician or dentist, to one (1) or more nonrelated persons who may be suffering from deformity, injury or disease or from any other condition for which nursing, medical or surgical services would be appropriate for care, diagnosis or treatment. All hospitals shall provide basic hospital functions and may provide optional services as delineated in these rules. A hospital shall be designated according to its classification and shall confine its services to those classifications described below.

(a) General Hospital. To be licensed as a general hospital, the institution shall maintain and operate organized facilities and services to accommodate one or more non-related persons for a period exceeding twenty-four (24) hours for the diagnosis, treatment or care of such persons and shall provide medical and surgical care of acute illness, injury or infirmity and obstetrical care. All diagnosis, treatment and care shall be administered by or performed under the direction of persons currently licensed to practice the healing arts in the State of Tennessee. In addition, a general hospital must specifically provide:

1. An organized staff of professional, technical and administrative personnel.

2. A laboratory with sufficient equipment and personnel necessary to perform biochemical, bacteriological, serological and parasitological tests.

3. X-ray facilities which shall include, as a minimum requirement, a complete diagnostic radiographic unit.

4. A separate surgical unit which shall include, as minimum requirements, one operating room, a sterilizing room, a scrub-up area and workroom.

5. Obstetrical facilities which shall include, as minimum requirements, one delivery room, a labor room, a newborn nursery, an isolation nursery, and patient rooms designated exclusively for obstetrical patients.

6. An emergency department in accordance with rule 1200-8-1-.07(5) of these standards and regulations.

(b) Satellite Hospital. A satellite hospital may be licensed with a parent hospital upon approval by the Board for Licensing Health Care Facilities when they are on separate premises and are operated under the same management.

(c) Chronic Disease Hospital. To be licensed as a chronic disease hospital, the institution shall be devoted exclusively to the diagnosis, treatment or care of persons needing medical, surgical or rehabilitative care for chronic or long-term illness, injury, or infirmity. The diagnosis,

(Rule 1200-8-1-.01, continued)

treatment or care shall be administered by or performed under the direction of persons currently licensed to practice the healing arts in the State of Tennessee. A chronic disease hospital shall meet the requirements for a general hospital except that obstetrical facilities are not required and, if the hospital provides no surgical services, an emergency department is not required.

(d) Orthopedic Hospital. To be licensed as an orthopedic hospital, the institution shall be devoted primarily to the diagnosis and treatment of orthopedic conditions. An orthopedic hospital shall meet the requirements for a general hospital except that obstetrical services are not required and, if the hospital provides no surgical services, an emergency department is not required.

(e) Pediatric Hospital. To be licensed as a pediatric hospital, the institution shall be devoted primarily to the diagnosis and treatment of pediatric cases and have on staff professional personnel especially qualified in the diagnosis and treatment of the diseases of children. A pediatric hospital shall meet the requirements of a general hospital except that obstetrical facilities are not required and if the hospital provides no surgical services, an emergency department is not required.

(f) Eye, Ear, Nose, and Throat Hospital or any one of these. To be licensed as an eye, ear, nose and throat hospital, the institution shall be devoted primarily to the diagnosis and treatment of the diseases of the eye, ear, nose, and throat. The hospital shall have on staff professional personnel especially qualified in the diagnosis and treatment of diseases of the eye, ear, nose and throat. An eye, ear, nose and throat hospital shall meet the requirements for a general hospital except that obstetrical facilities are not required and, if the hospital provides no surgical services, an emergency department is not required.

(g) Rehabilitation Hospital. To be licensed as a rehabilitation hospital, the institution shall be devoted primarily to the diagnosis and treatment of persons requiring rehabilitative services. A rehabilitation hospital shall meet the requirement of a general hospital except that radiology services, a surgical unit, obstetrical facilities, and an emergency department are not required.

(39) Hospitalization. The reception and care of any person for a continuous period longer than twenty-four (24) hours, for the purpose of giving advice, diagnosis, nursing service or treatment bearing on the physical health of such persons, and maternity care involving labor and delivery for any period of time.

(40) Incompetent. A patient who has been adjudicated incompetent by a court of competent jurisdiction and has not been restored to legal capacity.

(41) Individual instruction. An individual's direction concerning a health care decision for the individual.

(42) Infectious Waste. Solid or liquid wastes which contain pathogens with sufficient virulence and quantity such that exposure to the waste by a susceptible host could result in an infectious disease.

(43) Involuntary Transfer. The movement of a patient between hospitals, without the consent of the patient, the patient's legal guardian, next of kin or representative.

(44) Justified Emergency. Includes, but is not limited to, the following events/ occurrences:

(a) An influx of mass casualties;

(b) Localized and/or regional catastrophes such as storms, earthquakes, tornadoes, etc. or,

(c) Epidemics or episodes of mass illness such as influenza, salmonella, etc.

(Rule 1200-8-1-.01, continued)

(45) Licensed Clinical Social Worker. A person currently licensed as such by the Tennessee Board of Social Workers.

(46) Licensed Practical Nurse. A person currently licensed as such by the Tennessee Board of Nursing.

(47) Licensee. The person or entity to whom the license is issued. The licensee is held responsible for compliance with all rules and regulations.

(48) Life Threatening Or Serious Injury. Injury requiring the patient to undergo significant additional diagnostic or treatment measures.

(49) Medical Emergency. A medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in placing the patient's health in serious jeopardy, serious impairment to bodily functions or serious dysfunction of any bodily organ or part, which includes labor when delivery is imminent, when there is inadequate time to effect safe transfer to another hospital prior to delivery, or when a transfer may pose a threat to the health and safety of the patient or the unborn child.

(50) Medical Record. Medical histories, records, reports, summaries, diagnoses, prognoses, records of treatment and medication ordered and given, entries, x-rays, radiology interpretations. and other written electronics, or graphic data prepared, kept, made or maintained in a facility that pertains to confinement or services rendered to patients admitted or receiving care.

(51) Medical Staff. An organized body composed of individuals appointed by the hospital governing board that operates under bylaws approved by the governing body and is responsible for the quality of medical care provided to patients by the hospital. All members of the medical staff shall be licensed to practice in Tennessee, with the exception of interns and residents.

(52) Medically Inappropriate Treatment. Resuscitation efforts that cannot be expected either to restore cardiac or respiratory function to the patient or other medical or surgical treatments to achieve the expressed goals of the informed patient. In the case of the incompetent patient, the patient's representative expresses the goals of the patient.

(53) Member of the Professional Medical Community. A professional employed by the hospital and on the premises at the time of a voluntary delivery.

(54) Mid-Level Practitioner. Either a certified nurse practitioner or a physician assistant.

(55) N.F.P.A. The National Fire Protection Association.

(56) Nuclear Medicine Technologist. A person currently registered as such by the National Association for Nuclear Medicine Technology.

(57) Nurse Midwife. A person currently licensed by the Tennessee Board of Nursing as a registered nurse (R.N.) and qualified to deliver midwifery services or certified by the American College of Nurse-Midwives.

(58) Occupational Therapist. A person currently certified as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

(59) Occupational Therapy Assistant. A person currently certified as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

(60) Optometrist. A person currently licensed as such by the Tennessee Board of Optometry.

(Rule 1200-8-1-.01, continued)

(61) Patient. Includes but is not limited to any person who is suffering from an acute or chronic illness or injury or who is crippled, convalescent or infirm, or who is in need of obstetrical, surgical, medical, nursing or supervisory care.

(62) Patient Abuse. Patient neglect, intentional infliction of pain, injury, or mental anguish. Patient abuse includes the deprivation of services by a caretaker which are necessary to maintain the health and welfare of a patient or resident; however, the withholding of authorization for or provision of medical care to any terminally ill person who has executed an irrevocable living will in accordance with the Tennessee Right to Natural Death Law, or other applicable state law, if the provision of such medical care would conflict with the terms of such living will shall not be deemed "patient abuse" for purposes of these rules.

(63) Person. An individual, corporation, estate, trust, partnership, association, joint venture, government, governmental subdivision, agency, or instrumentality, or any other legal or commercial entity.

(64) Personally Informing. A communication by any effective means from the patient directly to a health care provider.

(65) Pharmacist. A person currently licensed as such by the Tennessee Board of Pharmacy.

(66) Physical Therapist. A person currently certified as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

(67) Physical Therapy Assistant. A person currently certified as such by the Tennessee Board of Occupational and Physical Therapy Examiners.

(68) Physician. An individual authorized to practice medicine or osteopathy under Tennessee Code Annotated, Title 63, Chapters 6 or 9.

(69) Physician Assistant. A person who is licensed by the Tennessee Board of Medical Examiners and Committee on Physician Assistants and has obtained prescription writing authority pursuant to T.C.A. 63-19-107(2)(A).

(70) Podiatrist. A person currently licensed as such by the Tennessee Board of Registration in Podiatry.

(71) Power of Attorney for Health Care. The designation of an agent to make health care decisions for the individual granting the power under T.C.A. Title 34, Chapter 6, Part 2.

(72) Psychologist. A person currently licensed as such by the Tennessee Board of Examiners in Psychology.

(73) Qualified Emergency Medical Service Personnel. Includes, but shall not be limited to, emergency medical technicians, paramedics, or other emergency services personnel, providers, or entities acting within the usual course of their professions, and other emergency responders.

(74) Radiological Technologist. A person currently registered as such by the American Society of Radiological Technologists.

(75) Reasonably Available. Readily able to be contacted without undue effort and willing and able to act in a timely manner considering the urgency of the patient's health care needs. Such availability shall include, but not be limited to, availability by telephone.

(76) Registered Nurse. A person currently licensed as such by the Tennessee Board of Nursing.

(Rule 1200-8-1-.01, continued)

(77) Registered Record Administrator (RRA). A person currently registered as such by the American Medical Record Association.

(78) Satellite Hospital. A freestanding hospital licensed with a parent hospital that is on separate premises and operated under the same management.

(79) Shall or Must. Compliance is mandatory.

(80) Social Worker. A person who has at least a bachelor's degree in Social Work or related field, and preferably, two (2) years medical social work or other community based work experience.

(81) Stabilize. To provide such medical treatment of the emergency medical condition as may be necessary to assure, within reasonable medical probability, that the condition will not materially deteriorate due to the transfer as determined by a physician or other qualified medical personnel when a physician is not readily available.

(82) State. A state of the United States, the District of Columbia, the Commonwealth of Puerto Rico, or a territory or insular possession subject to the jurisdiction of the United States.

(83) Student. A person currently enrolled in a course of study that is approved by the appropriate licensing board.

(84) Supervising Health Care Provider. The designated physician or, if there is no designated physician or the designated physician is not reasonably available, the health care provider who has undertaken primary responsibility for an individual's health care.

(85) Surgical Technologist. A person who currently holds a national certification by the Liaison Council on Certification for the Surgical Technologist (LCC-ST); or has completed a program for surgical technologists accredited by the Commission on Accreditation of Allied Health Education Programs (CAAHEP); or has completed an appropriate training program for surgical technologists in the armed forces; or has successfully completed the LCC-ST certifying exam; or provides sufficient evidence that prior to July 1, 2006, the person began training or was at any time employed as a surgical technologist for not less than eighteen (18) months in a hospital, medical office, surgery center or school.

(86) Surrogate. An individual, other than a patient's agent or guardian, authorized to make a health care decision for the patient.

(87) Transfer. The movement of a patient between hospitals at the direction of a physician or other qualified medical personnel when a physician is not readily available but does not include such movement of a patient who leaves the facility against medical advice. The term does not apply to the commitment and movement of mentally ill and mentally retarded persons and does not apply to the discharge or release of a patient no longer in medical need of hospital care or to a hospital's refusal, after an appropriate medical screening, to render any medical care on the grounds that the person does not have a medical need for hospital care.

(88) Treating Health Care Provider. A health care provider who at the time is directly or indirectly involved in providing health care to the patient.

(89) Treating Physician. The physician selected by or assigned to the patient and who has the primary responsibility for the treatment and care of the patient. Where more than one physician shares such responsibility, any such person may be deemed to be the "treating physician."

(90) Universal Do Not Resuscitate Order. A written order that applies regardless of the treatment setting and that is signed by the patient's physician which states that in the event the patient suffers cardiac or

(Rule 1200-8-1-.01, continued)

respiratory arrest, cardiopulmonary resuscitation should not be attempted. The Physician Order for Scope of Treatment (POST) form promulgated by the Board for Licensing Health Care Facilities as a mandatory form shall serve as the Universal DNR according to these rules.

(91) Unusual Event. The abuse of a patient or an unexpected occurrence or accident that results in death, life threatening or serious injury to a patient that is not related to a natural course of the patient's illness or underlying condition.

(92) Unusual Event Report. A report form designated by the department to be used for reporting an unusual event.

(93) Voluntary Delivery. The action of a mother in leaving an unharmed infant aged seventy-two (72) hours or younger on the premises of a hospital with any hospital employee or member of the professional medical community without expressing any intention to return for such infant, and failing to visit or seek contact with such infant for a period of thirty (30) days thereafter.

Authority: *T.C.A. §§4-5-202, 4-5-204, 39-11-106, 68-11-202, 68-11-204, 68-11-207, 68-11-209, 68-11-210, 68-11-211, 68-11-213, 68-11-224, 68-11-255, 68-11-1802, 68-57-101, and 68-57-102.* ***Administrative History:*** *Original rule certified June 7, 1974. Amendment filed April 3, 1974; effective May 3, 1974. Amendment filed November 30, 1984; effective December 30, 1984. Repeal and new rule filed May 22, 1986; effective June 21, 1986. Amendment filed April 26, 1996; effective July 8, 1996. Amendment filed November 30, 1999; effective February 6, 2000. Repeal, except for Paragraphs (1), (5), (8), (10), (11), (13), (16), (29) and (37) as promulgated February 6, 2000, and new rule filed March 18, 2000; effective May 30, 2000. Amendment filed April 17, 2000; effective July 1, 2000. Amendment filed September 17, 2002; effective December 1, 2002. Amendment filed April 11, 2003; effective June 25, 2003. Amendment filed April 28, 2003; effective July 12, 2003. Amendment filed August 27, 2004; effective November 10, 2004. Amendments filed September 6, 2005; effective November 20, 2005. Amendment filed February 23, 2006; effective May 9, 2006. Amendment filed February 7, 2007; effective April 23, 2007.*

1200-8-1-.02 LICENSING PROCEDURES.

(1) No person, partnership, association, corporation, or state, county or local government unit, or division, department, board or agency thereof, shall establish, conduct, operate, or maintain in the State of Tennessee any hospital without having a license. A license shall be issued only to the applicant named and only for the premises listed in the application for licensure. Licenses are not transferable or assignable and shall expire annually on June 30th. The license shall be conspicuously posted in the hospital.

(2) In order to make application for a license:

(a) The applicant shall submit an application on a form prepared by the department.

(b) Each applicant for a license shall pay an annual license fee based on the number of hospital beds. The fee must be submitted with the application and is not refundable.

(c) The issuance of an application form is in no way a guarantee that the completed application will be accepted or that a license will be issued by the department. Patients shall not be admitted to the hospital until a license has been issued. Applicants shall not hold themselves out to the public as being a hospital until the license has been issued. A license shall not be issued until the facility is in substantial compliance with these rules and regulations including submission of all information required by T.C.A. §68-11-206(1), or as later amended, and of all information required by the Commissioner.

(d) The applicant must prove the ability to meet the financial needs of the facility.

(Rule 1200-8-1-.02, continued)

(e) The applicant shall not use subterfuge or other evasive means to obtain a license, such as filing for a license through a second party when an individual has been denied a license or has had a license disciplined or has attempted to avoid inspection and review process.

(3) A proposed change of ownership, including a change in a controlling interest, must be reported to the department a minimum of thirty (30) days prior to the change. A new application and fee must be received by the department before the license may be issued.

(a) For the purposes of licensing, the licensee of a hospital has the ultimate responsibility for the operation of the facility, including the final authority to make or control operational decisions and legal responsibility for the business management. A change of ownership occurs whenever this ultimate legal authority for the responsibility of the hospital's operation is transferred.

(b) A change of ownership occurs whenever there is a change in the legal structure by which the hospital is owned and operated.

(c) Transactions constituting a change of ownership include, but are not limited to, the following:

1. Transfer of the facility's legal title;

2. Lease of the facility's operations;

3. Dissolution of any partnership that owns, or owns a controlling interest in, the facility;

4. One partnership is replaced by another through the removal, addition or substitution of a partner;

5. Removal of the general partner or general partners, if the facility is owned by a limited partnership;

6. Merger of a facility owner (a corporation) into another corporation where, after the merger, the owner's shares of capital stock are cancelled;

7. The consolidation of a corporate facility owner with one or more corporations; or,

8. Transfers between levels of government.

(d) Transactions which do not constitute a change of ownership include, but are not limited to, the following:

1. Changes in the membership of a corporate board of directors or board of trustees;

2. Two (2) or more corporations merge and the originally-licensed corporation survives;

3. Changes in the membership of a non-profit corporation;

4. Transfers between departments of the same level of government; or,

5. Corporate stock transfers or sales, even when a controlling interest.

(e) Management agreements are generally not changes of ownership if the owner continues to retain ultimate authority for the operation of the facility. However, if the ultimate authority is surrendered and transferred from the owner to a new manager, then a change of ownership has occurred.

(Rule 1200-8-1-.02, continued)

(f) Sale/lease-back agreements shall not be treated as changes in ownership if the lease involves the facility's entire real and personal property and if the identity of the leasee, who shall continue the operation, retains the exact same legal form as the former owner.

(4) Each hospital, except those operated by the U.S. Government or the State of Tennessee, making application for license under this chapter shall pay annually to the department a fee based on the number of hospital beds, as follows:

(a)	Less than 25 beds	$ 800.00
(b)	25 to 49 beds, inclusive	$ 1,000.00
(c)	50 to 74 beds, inclusive	$ 1,200.00
(d)	75 to 99 beds, inclusive	$ 1,400.00
(e)	100 to 124 beds, inclusive	$ 1,600.00
(f)	125 to 149 beds, inclusive	$ 1,800.00
(g)	150 to 174 beds, inclusive	$ 2,000.00
(h)	175 to 199 beds, inclusive	$ 2,200.00

For hospitals of two hundred (200) beds or more the fee shall be two thousand four hundred dollars ($2,400.00) plus two hundred dollars ($200.00) for each twenty-five (25) beds or fraction thereof in excess of one hundred ninety-nine (199) beds. The fee shall be submitted with the application or renewal and is not refundable.

(5) To be eligible for a license or renewal of a license, each hospital shall be periodically inspected for compliance with these regulations. If deficiencies are identified, an acceptable plan of correction must be submitted.

Authority: *T.C.A. §§4-5-201, 4-5-202, 4-5-204, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.* ***Administrative History:*** *Original rule certified June 7, 1974. Repeal and new rule filed May 22, 1986; effective June 21, 1986. Amendment filed January 16, 1992; effective March 2, 1992. Repeal and new rule filed March 18, 2000; effective May 30, 2000. Amendment filed December 2, 2003; effective February 15, 2004. Amendment filed January 19, 2007; effective April 4, 2007.*

1200-8-1-.03 DISCIPLINARY PROCEDURES.

(1) The board may suspend or revoke a license for:

(a) Violation of federal or state statutes;

(b) Violation of the rules as set forth in this chapter;

(c) Permitting, aiding or abetting the commission of any illegal act in the hospital;

(d) Conduct or practice found by the board to be detrimental to the health, safety, or welfare of the patients of the hospital; and

(e) Failure to renew license.

(Rule 1200-8-1-.03, continued)

(2) The board may consider all factors which it deems relevant, including but not limited to the following when determining sanctions:

(a) The degree of sanctions necessary to ensure immediate and continued compliance;

(b) The character and degree of impact of the violation on the health, safety and welfare of the patients in the facility;

(c) The conduct of the facility in taking all feasible steps or procedures necessary or appropriate to comply or correct the violation; and

(d) Any prior violations by the facility of statutes, regulations or orders of the board.

(3) Inappropriate transfers are prohibited and violation of the transfer provisions shall be deemed sufficient grounds to suspend or revoke a hospital's license.

(4) When a hospital is found by the department to have committed a violation of this chapter, the department will issue to the facility a statement of deficiencies. Within ten (10) days of the receipt of the deficiencies, the hospital must return a plan of correction indicating the following:

(a) How the deficiency will be corrected;

(b) The date upon which each deficiency will be corrected;

(c) What measures or systemic changes will be put in place to ensure that the deficient practice does not recur; and

(d) How the corrective action will be monitored to ensure that the deficient practice does not recur.

(5) Either failure to submit a plan of correction in a timely manner or a finding by the department that the plan of correction is unacceptable shall subject the hospital's license to possible disciplinary action.

(6) Any licensee or applicant for a license, aggrieved by a decision or action of the department or board, pursuant to this chapter, may request a hearing before the board. The proceedings and judicial review of the board's decision shall be in accordance with the Uniform Procedures Act, T.C.A. §4-5-101, et seq.

(7) Reconsideration and Stays. The Board authorizes the member who chaired the Board for a contested case to be the agency member to make the decisions authorized pursuant to rule 1360-4-1-.18 regarding petitions for reconsiderations and stays in that case.

Authority: *T.C.A. §§4-5-202, 4-5-204, 4-5-219, 4-5-312, 4-5-316, 4-5-317, 68-11-202, 68-11-204, 68-11-206, 68-11-208, 68-11-209, and 68-11-216.* ***Administrative History:*** *Original rule certified June 7, 1974. Amendment filed April 3, 1974; effective May 3, 1974. The following is a copy of T.C.A. §53-1317: Amendment filed February 26, 1985; effective March 28, 1985. Repeal and new rule filed May 22, 1986; effective June 21, 1986. Amendment filed December 30, 1986; effective February 13, 1987. Repeal and new rule filed March 18, 2000; effective May 30, 2000. Amendment filed March 1, 2007; effective May 15, 2007.*

1200-8-1-.04 ADMINISTRATION.

(1) The hospital must have an effective governing body legally responsible for the conduct of the hospital. If a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this chapter.

(Rule 1200-8-1-.04, continued)

(2) The governing body shall appoint a chief executive officer or administrator who is responsible for managing the hospital. The chief executive officer or administrator shall designate an individual to act for him or her in his or her absence, in order to provide the hospital with administrative direction at all times.

(3) When licensure is applicable for a particular job, the number and renewal number of the current license must be maintained in personnel. Each personnel file shall contain accurate information as to the education, training, experience and personnel background of the employee. Adequate medical screenings to exclude communicable disease shall be required of each employee.

(4) Whenever the rules and regulations of this chapter require that a licensee develop a written policy, plan, procedure, technique, or system concerning a subject, the licensee shall develop the required policy, maintain it and adhere to its provisions. A hospital which violates a required policy also violates the rule and regulation establishing the requirement.

(5) Policies and procedures shall be consistent with professionally recognized standards of practice.

(6) No hospital shall retaliate against or, in any manner, discriminate against any person because of a complaint made in good faith and without malice to the board, the department, the Adult Protective Services, or the Comptroller of the State Treasury. A hospital shall neither retaliate, nor discriminate, because of information lawfully provided to these authorities, because of a person's cooperation with them, or because a person is subpoenaed to testify at a hearing involving one of these authorities.

(7) The hospital shall ensure a framework for addressing issues related to care at the end of life.

(8) The hospital shall provide a process that assesses pain in all patients. There shall be an appropriate and effective pain management program.

(9) Critical Access Hospital.

(a) The facility shall enter into agreements with one or more hospitals participating in the Medicare/Medicaid programs to provide services which the Critical Access Hospital is unable to provide.

(b) When there are no inpatients, the facility is not required to be staffed by licensed medical professionals, but must maintain a receptionist or other staff person on duty to provide emergency communication access. The hospital shall provide an effective system to ensure that a physician or a mid-level practitioner with training and experience in emergency care is on call and immediately available by telephone or radio and available on site within thirty (30) minutes, twenty-four (24) hours a day.

(10) All health care facilities licensed pursuant to T.C.A. §§ 68-11-201, et seq. shall post the following in the main public entrance:

(a) Contact information including statewide toll-free number of the division of adult protective services, and the number for the local district attorney's office;

(b) A statement that a person of advanced age who may be the victim of abuse, neglect, or exploitation may seek assistance or file a complaint with the division concerning abuse, neglect and exploitation; and

(c) A statement that any person, regardless of age, who may be the victim of domestic violence may call the nationwide domestic violence hotline, with that number printed in boldface type, for immediate assistance and posted on a sign no smaller than eight and one-half inches (8½") in width and eleven inches (11") in height.

(Rule 1200-8-1-.04, continued)

Postings of (a) and (b) shall be on a sign no smaller than eleven inches (11") in width and seventeen inches (17") in height.

(11) Hospice services may be provided in an area designated by a hospital for exclusive use by a home care organization certified as a hospice provider to provide care at the hospice inpatient or respite level of care in accordance with the hospice's Medicare certification. Admission to the hospital is not required in order for a patient to receive such hospice services, regardless of the patient's length of stay. The designation by a hospital of a portion of its facility for exclusive use by a home care organization to provide hospice services to its patients shall not:

(a) alter the license to bed complement of such hospital, or

(b) result in the establishment of a residential hospice.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-216, and 71-6-121.* ***Administrative History:*** *Original rule filed March 18, 2000; effective May 30, 2000. Amendment filed June 18, 2002; effective September 1, 2002. Amendment filed December 2, 2003; effective February 15, 2004. Amendment filed April 20, 2006; effective July 4, 2006. Amendment filed February 23, 2007; effective May 9, 2007. Amendment filed July 18, 2007; effective October 1, 2007.*

1200-8-1-.05 ADMISSIONS, DISCHARGES, AND TRANSFERS.

(1) Every person admitted for care or treatment to any hospital covered by these rules shall be under the supervision of a physician who holds an unlimited license to practice in Tennessee. The name of the patient's attending physician shall be recorded in the patient's medical record.

(2) The above does not preclude the admission of a patient to a hospital by a dentist or podiatrist or certified nurse midwife licensed to practice in Tennessee with the concurrence of a physician member of the medical staff.

(3) This does not preclude qualified oral and maxillo-facial surgeons from admitting patients and completing the admission history and physical examination and assessing the medical risk of the procedure on their patients. A physician member of the medical staff is responsible for the management of medical problems.

(4) A diagnosis must be entered in the admission records of the hospital for every person admitted for care or treatment.

(5) Except in emergencies, no medication or treatment shall be given or administered to any patient in a hospital except on the order of a physician, dentist or podiatrist lawfully authorized to give such an order.

(6) The facility shall ensure that no person on the grounds of race, color, national origin, or handicap, will be excluded from participation in, be denied benefits of, or otherwise subjected to discrimination in the provision of any care or service of the facility. The facility shall protect the civil rights of residents under the Civil Rights Act of 1964 and Section 504 of the Rehabilitation Act of 1973.

(7) For purposes of this chapter, the requirements for signature or countersignature by a physician, dentist, podiatrist or other person responsible for signing, countersigning or authenticating an entry may be satisfied by the electronic entry by such person of a unique code assigned exclusively to him or her, or by entry of other unique electronic or mechanical symbols, provided that such person has adopted same as his or her signature in accordance with established hospital protocol or rules.

(Rule 1200-8-1-.05, continued)

(8) The hospital must ensure continuity of care and provide an effective discharge planning process that applies to all patients. The hospital's discharge planning process, including discharge policies and procedures, must be specified in writing and must:

(a) Be developed and/or supervised by a registered nurse, social worker or other appropriately qualified personnel;

(b) Begin upon admission of any patient who is likely to suffer adverse health consequences;

(c) Be provided when identified as a need by the patient, a person acting on the patient's behalf, or by the physician;

(d) Include the likelihood of a patient's capacity for self-care or the possibility of the patient returning to his or her pre-hospitalization environment;

(e) Identify the patient's continuing physical, emotional, housekeeping, transportation, social and other needs and must make arrangements to meet those needs;

(f) Be completed on a timely basis to allow for arrangement of post-hospital care and to avoid unnecessary delays in discharge;

(g) Involve the patient, the patient's family or individual acting on the patient's behalf, the attending physician, nursing and social work professionals and other appropriate staff, and must be documented in the patient's medical record; and

(h) Be conducted on an ongoing basis throughout the continuum of hospital care. Coordination of services may involve promoting communication to facilitate family support, social work, nursing care, consultation, referral or other follow-up.

(9) A discharge plan is required on every patient, even if the discharge is to home.

(10) The hospital must arrange for the initial implementation of the patient's discharge plan and must reassess the patient's discharge plan if there are factors that may affect continuing care needs or the appropriateness of the discharge plan.

(11) As needed, the patient and family members or interested persons must be taught and/or counseled to prepare them for post-hospital care.

(12) The hospital must transfer or refer patients, along with necessary medical information, to appropriate facilities, agencies, or outpatient services, as needed, for follow-up or ancillary care.

(13) The governing body of each hospital must adopt transfer and acceptance policies and procedures in accordance with these rules and the provisions of T.C.A. §§ 68-11-701 through 68-11-705. These policies must include a review of all such involuntary transfers, with special emphasis on those originating in the emergency room.

(14) Transfer agreements with other health care facilities are subject to these statutory and regulatory provisions.

(15) When a hospital proceeding in compliance with these rules seeks to appropriately transfer a patient to another hospital, the proposed receiving hospital may not decline the transfer for reasons related to the patient's ability to pay or source of payment, rather than the patient's need for medical services. The determination of the availability of space at the receiving hospital may not be based on the patient's ability to pay or source of payment.

(Rule 1200-8-1-.05, continued)

(16) Anyone arriving at a hospital and/or the emergency department of a hospital requesting or requiring an examination or treatment for a medical condition must be provided an appropriate medical screening examination within the capability of the hospital's staff to determine whether or not a medical emergency exists.

(17) The hospital must provide further medical examination and treatment as may be required to stabilize the medical emergency within the hospital's available staff and facilities. Such treatment may include, but is not limited to, the following:

(a) Establishing and assuring an adequate airway and adequate ventilation;

(b) Initiating control of hemorrhage;

(c) Stabilizing and splinting the spine or fractures;

(d) Establishing and maintaining adequate access routes for fluid administration;

(e) Initiating adequate fluid and/or blood replacement; and

(f) Determining that the patient's vital signs (including blood pressure, pulse, respiration, and urinary output, if indicated) are sufficient to sustain adequate perfusion.

(18) A hospital is deemed to meet the requirements of this section with respect to an individual if:

(a) The hospital offers to provide the further medical examination and treatment necessary but the individual, or legally responsible person acting on the individual's behalf, refuses to consent to the examination or treatment; or

(b) The hospital offers to transfer the individual to another hospital in accordance with this section but the individual, or legally responsible person acting on the individual's behalf, refuses to consent to the transfer.

(19) If a patient at a hospital has not been or cannot be stabilized within the meaning of this section, the hospital may not transfer the patient unless:

(a) The patient, or legally responsible person acting on the patient's behalf, requests that a transfer be implemented after having been given complete and accurate information about matters pertaining to the transfer decision including:

1. The medical necessity of the movement;

2. The availability of appropriate medical services at both the transferring and receiving hospitals;

3. The availability of indigent care at the hospital initiating the transfer and the facility's legal obligations, if any, to provide medical services without regard to the patient's ability to pay; and,

4. Any obligation of the hospital through its participation in medical assistance programs of the federal, state or local government to accept the medical assistance program's reimbursement as payment in full for the needed medical care.

(b) A physician, or other appropriately qualified medical personnel when a physician is not available, makes a determination based upon the reasonable risk, expected benefits to the patient, and current available information that the medical benefits reasonably expected from

(Rule 1200-8-1-.05, continued)

the provision of appropriate medical treatment at another hospital outweigh the increased risk to the individual's medical condition resulting from a transfer; and

(c) The transfer is appropriate within the meaning of this section.

(20) An appropriate transfer includes:

(a) A physician at the receiving hospital agreeing to accept transfer of the patient and to provide appropriate medical treatment;

(b) The receiving hospital having space available and personnel qualified to treat the patient;

(c) The transferring hospital providing the receiving hospital with appropriate medical records, or copies thereof, of any examination and/or treatment initiated by the transferring hospital; and

(d) The transfer being effected with qualified personnel, appropriate transportation equipment, and the use of necessary and medically appropriate life support measures as required.

(21) Transfers made pursuant to a regionalized plan for the delivery of health care services, approved by the department or other authorized governmental planning agency, are presumed to be appropriate.

(22) After an appropriate transfer has been effected, the receiving hospital may transfer the patient back to the original hospital, and the original hospital may accept the patient, if:

(a) The original receiving hospital has stabilized the medical emergency or provided treatment of the active labor and the patient no longer has a medical emergency; and

(b) The transfer is made in accordance with (21) of this section.

(23) When a hospital determines the need to exceed its licensed bed capacity upon an occurrence of a justified emergency, the following procedures must be followed:

(a) The hospital's administrator must make written notification to the Department within forty-eight (48) hours of exceeding its licensed bed capacity.

(b) The notification must include a detailed description of the emergency including:

1. Why the licensed bed capacity was exceeded, i.e., lack of hospital beds in vicinity, specialized resources only available at the facility, etc.;

2. The estimated length of time the licensed bed capacity is expected to be exceeded; and,

3. The number of admissions in excess of the facility's licensed bed capacity.

(c) As soon as the hospital returns to its licensed bed capacity, the administrator must notify the department in writing of the effective date of its return to compliance.

(d) Staff will review all notifications of excess bed capacity with the Chairman of the Board. If, upon review of the notification, department staff concurs that a justified emergency existed, staff will notify the facility in writing. A report of the occurrence will be made to the board at the next regularly scheduled meeting as information purposes only.

(e) However, if department staff does not concur that a justified emergency existed, the facility will be notified in writing that a representative is required to appear at the next regularly scheduled board meeting to justify the need for exceeding its licensed bed capacity.

(Rule 1200-8-1-.05, continued)

(24) Infant Abandonment.

(a) Any hospital shall receive possession of any newborn infant left on hospital premises with any hospital employee or member of the professional medical community, if the infant:

1. Was born within the preceding seventy-two (72) hour period, as determined within a reasonable degree of medical certainty;

2. Is left in an unharmed condition; and

3. Is voluntarily left by a person who purported to be the child's mother and who did not express an intention of returning for the infant.

(b) The hospital, any hospital employee and any member of the professional medical community at such hospital shall inquire whenever possible about the medical history of the mother or newborn and whenever possible shall seek the identity of the mother, infant, or the father of the infant. The hospital shall also inform the mother that she is not required to respond, but that such information will facilitate the adoption of the child. Any information obtained concerning the identity of the mother, infant or other parent shall be kept confidential and may only be disclosed to the Department of Children's Services. The hospital may provide the parent contact information regarding relevant social service agencies, shall provide the mother the name, address and phone number of the department contact person, and shall encourage the mother to involve the Department of Children's Services in the relinquishment of the infant. If practicable, the hospital shall also provide the mother with both orally delivered and written information concerning the requirements of these rules relating to recovery of the child and abandonment of the child.

(c) The hospital, any hospital employee and any member of the professional medical community at such hospital shall perform any act necessary to protect the physical health or safety of the child.

(d) As soon as reasonably possible, and no later than twenty-four (24) hours after receiving a newborn infant, the hospital shall contact the Department of Children's Services, but shall not do so before the mother leaves the hospital premises. Upon receipt of notification, the department shall immediately assume care, custody and control of the infant.

(e) Notwithstanding any provision of law to the contrary, any hospital, any hospital employee and any member of the professional medical community shall be immune from any criminal or civil liability for damages as a result of any actions taken pursuant to the requirements of these rules, and no lawsuit shall be predicated thereon; provided, however, that nothing in these rules shall be construed to abrogate any existing standard of care for medical treatment or to preclude a cause of action based upon violation of such existing standard of care for medical treatment.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-209, and 68-11-255.* ***Administrative History:*** *Original rule filed March 18, 2000; effective May 30, 2000. Amendment filed April 17, 2000; effective July 1, 2000. Amendment filed September 17, 2002; effective December 1, 2002.*

1200-8-1-.06 BASIC HOSPITAL FUNCTIONS.

(1) Performance Improvement.

(a) The hospital must ensure that there is an effective, hospital-wide performance improvement program to evaluate and continually improve patient care and performance of the organization.

(Rule 1200-8-1-.06, continued)

(b) The performance improvement program must be ongoing and have a written plan of implementation which assures that:

1. All organized services including services furnished by a contractor, are evaluated (all departments including engineering, housekeeping, and accounting need to show evidence of process improvement.);

2. Nosocomial infections and medication therapy are evaluated;

3. All medical and surgical services performed in the hospital are evaluated as to the appropriateness of diagnosis and treatment;

4. The competency of all staff is evaluated at least annually; and

5. The facility shall develop and implement a system for measuring improvements in adherence to the hand hygiene program, central venous catheter insertion process, and influenza vaccination program.

(c) The hospital must have an ongoing plan, consistent with available community and hospital resources, to provide or make available social work, psychological, and educational services to meet the medically-related needs of its patients which assures that:

1. Discharge planning is initiated in a timely manner; and

2. Patients, along with their necessary medical information, are transferred or referred to appropriate facilities, agencies or outpatient services, as needed, for follow-up or ancillary care.

(d) The hospital must develop and implement plans for improvement to address deficiencies identified by the performance improvement program and must document the outcome of the remedial action.

(e) The hospital must demonstrate that the appropriate governing board or board committee is regularly apprised of process improvement activities, including identified deficiencies and the outcomes of remedial action.

(2) Medical Staff.

(a) The hospital shall have an organized medical staff operating under bylaws adopted by the medical staff and approved by the governing body, to facilitate the medical staff's responsibility in working toward improvement of the quality of patient care.

(b) The hospital and medical staff bylaws shall contain procedures, governing decisions or recommendations of appropriate authorities concerning the granting, revocation, suspension, and renewal of medical staff appointments, reappointments, and/or delineation of privileges. At a minimum, such procedures shall include the following elements: A procedure for appeal and hearing by the governing body or other designated committee if the applicant or medical staff feels the decision is unfair or wrong.

(c) The governing body shall be responsible for appointing medical staff and for delineating privileges. Criteria for appointment and delineation of privileges shall be clearly defined and included in the medical staff bylaws, and related to standards of patient care, patient welfare, the objectives of the institution or the character or competency of the individual practitioner. Independent patient admission privileges shall only be granted to currently licensed doctors of medicine, osteopathy, podiatry, or dentistry.

(Rule 1200-8-1-.06, continued)

(d) The medical staff must adopt and enforce bylaws to effectively carry out its responsibilities and the bylaws must:

1. Be approved by the governing body;

2. Include a statement of the duties and privileges of each category of medical staff;

3. Describe the organization of the medical staff;

4. Describe the qualifications to be met by a candidate in order for the medical staff to recommend that the candidate be appointed by the governing body;

5. Include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges; and

6. Include provisions for medical staff appointments granting active, associate, or courtesy medical staff membership, and/or provisions for the granting of clinical privileges. Such individuals must practice within the scope of their current Tennessee license, and the overall care of each patient must be under the supervision of a physician member of the medical staff.

(e) To be eligible for staff membership, an applicant must be a graduate of an approved program of medicine, dentistry, osteopathy, podiatry, optometry, psychology, or nurse-midwifery, currently licensed in Tennessee, competent in his or her respective field, and worthy in character and in matters of professional ethics.

(f) The medical staff shall be composed of currently licensed doctors of medicine, osteopathy, dentistry, and podiatry and may include optometrists, psychologists, and nurse-midwives. The medical staff must:

1. Periodically conduct appraisals of its members;

2. Examine the credentials of candidates for medical staff membership and make recommendations to the hospital on the appointment of the candidates; and

3. Participate actively in the hospital's process improvement plan implementation for the improvement of patient care delivery plans.

(g) The medical staff must be structured in a manner approved by the hospital or its governing body, well organized, and accountable to the hospital for the quality of the medical care provided to the patient. Disciplinary action involving medical staff taken by the hospital shall be reported to the appropriate licensing board or professional society.

(h) If the medical staff has an executive committee, a majority of the members of the committee must be doctors of medicine or osteopathy.

(i) The responsibility for organization and conduct of the medical staff must be assigned only to an individual doctor of medicine or osteopathy, or a doctor of dental surgery or dental medicine.

(j) All physicians and non-employee medical personnel working in the hospital must adhere to the policies and procedures of the hospital. The chief executive officer or his or her designee shall provide for the adequate supervision and evaluation of the clinical activities of non-employee medical personnel which occur within the responsibility of the medical staff service.

(Rule 1200-8-1-.06, continued)

(3) Infection Control.

(a) The hospital must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active performance improvement program for the prevention, control, and investigation of infections and communicable diseases.

(b) The chief executive officer or administrator shall assure that an infection control committee including members of the medical staff, nursing staff and administrative staff develop guidelines and techniques for the prevention, surveillance, control and reporting of hospital infections. Duties of the committee shall include the establishment of:

1. Written infection control policies;

2. Techniques and systems for identifying, reporting, investigating and controlling infections in the hospital;

3. Written procedures governing the use of aseptic techniques and procedures in all areas of the hospital, including adoption of a standardized central venous catheter insertion process which shall contain these key components:

(i) Hand hygiene (as defined in 1200-8-1-.06(3)(g));

(ii) Maximal barrier precautions to include the use of sterile gowns, gloves, mask and hat, and large drape on patient;

(iii) Chlorhexidine skin antisepsis;

(iv) Optimal site selection;

(v) Daily review of line necessity; and

(vi) Development and utilization of a procedure checklist;

4. Written procedures concerning food handling, laundry practices, disposal of environmental and patient wastes, traffic control and visiting rules in high risk areas, sources of air pollution, and routine culturing of autoclaves and sterilizers;

5. A log of incidents related to infectious and communicable diseases;

6. A method of control used in relation to the sterilization of supplies and water, and a written policy addressing reprocessing of sterile supplies;

7. Formal provisions to educate and orient all appropriate personnel in the practice of aseptic techniques such as handwashing and scrubbing practices, proper grooming, masking and dressing care techniques, disinfecting and sterilizing techniques, and the handling and storage of patient care equipment and supplies; and

8. Continuing education provided for all hospital personnel on the cause, effect, transmission, prevention, and elimination of infections, as evidenced by front line employees verbalizing understanding of basic techniques.

(c) The administrative staff shall ensure the hospital prepares, and has readily available on site, an Infection Control Risk Assessment for any renovation or construction within existing hospitals. Components of the Infection Control Risk Assessment may include, but are not limited to, identification of the area to be renovated or constructed, patient risk groups that will potentially

(Rule 1200-8-1-.06, continued)

be affected, precautions to be implemented, utility services subject to outages, risk of water damage, containment measures, work hours for project, management of traffic flow, housekeeping, barriers, debris removal, plans for air sampling during or following project, anticipated noise or vibration generated during project.

(d) The chief executive officer, the medical staff and the chief nursing officer must ensure that the hospitalwide performance improvement program and training programs address problems identified by the infection control committee and must be responsible for the implementation of successful corrective action plans in affected problem areas.

(e) The facility shall develop policies and procedures for testing a patient's blood for the presence of the hepatitis B virus and the HIV (AIDS) virus in the event that an employee of the facility, a student studying at the facility, or other health care provider rendering services at the facility is exposed to a patient's blood or other body fluid. The testing shall be performed at no charge to the patient, and the test results shall be confidential.

(f) The facility shall have an annual influenza vaccination program which shall include at least:

1. The offer of influenza vaccination to all staff and independent practitioners or accept documented evidence of vaccination from another vaccine source or facility;

2. A signed declination statement on record from all who refuse the influenza vaccination for other than medical contraindications;

3. Education of all direct care personnel about the following:

(i) Flu vaccination,

(ii) Non-vaccine control measures, and

(iii) The diagnosis, transmission, and potential impact of influenza;

4. An annual evaluation of the influenza vaccination program and reasons for non-participation;

5. The requirements to complete vaccinations or declination statements are suspended by the Medical Director in the event of a vaccine shortage.

(g) The facility and its employees shall adopt and utilize standard precautions (per CDC) for preventing transmission of infections, HIV, and communicable diseases, including adherence to a hand hygiene program which shall include:

1. Use of alcohol-based hand rubs or use of non-antimicrobial or antimicrobial soap and water before and after each patient contact if hands are not visibly soiled;

2. Use of gloves during each patient contact with blood or where other potentially infectious materials, mucous membranes, and non-intact skin could occur and gloves changed before and after each patient contact;

3. Use of either a non-antimicrobial soap and water or an antimicrobial soap and water for visibly soiled hands; and

4. Health care worker education programs which may include:

(i) Types of patient care activities that can result in hand contamination;

(Rule 1200-8-1-.06, continued)

(ii) Advantages and disadvantages of various methods used to clean hands;

(iii) Potential risks of health care workers' colonization or infection caused by organisms acquired from patients; and

(iv) Morbidity, mortality, and costs associated with health care associated infections.

(h) All hospitals shall adopt appropriate policies regarding the testing of patients and staff for human immunodeficiency virus (HIV) and any other identified causative agent of acquired immune deficiency syndrome.

(i) Each department of the hospital performing decontamination and sterilization activities must develop policies and procedures in accordance with the current editions of the CDC guidelines for "Prevention and Control of Nosocomial Diseases" and "Isolation in Hospitals".

(j) The central sterile supply area(s) shall be supervised by an employee, qualified by education and/or experience with a basic knowledge of bacteriology and sterilization principles, who is responsible for developing and implementing written policies and procedures for the daily operation of the central sterile supply area, including:

1. Receiving, decontaminating, cleaning, preparing, and disinfecting or sterilizing reusable items;

2. Assembling, wrapping, removal of outer shipping cartons, storage, distribution, and quality control of sterile equipment and medical supplies;

3. Proper utilization of sterilization process monitors, including temperature and pressure recordings, and use and frequency of appropriate chemical indicator or bacteriological spore tests for all sterilizers; and

4. Provisions for maintenance of package integrity and designation of event-related shelf life for hospital-sterilized and commercially prepared supplies;

5. Procedures for recall and disposal or reprocessing of sterile supplies; and

6. Procedures for emergency collection and disposition of supplies and the timely notification of attending physicians, general medical staff, administration and the hospital's risk management program when special warnings have been issued or when warranted by the hospital's performance improvement process.

(k) Precautions shall be taken to prevent the contamination of sterile supplies by soiled supplies. Sterile supplies shall be packaged and stored in a manner that protects the sterility of the contents. Sterile supplies may not be stored in their outermost shipping carton. This would include both hospital and commercially prepared supplies. Decontamination and preparation areas shall be separated.

(l) Space and facilities for housekeeping equipment and supply storage shall be provided in each hospital service area. Storage for bulk supplies and equipment shall be located away from patient care areas. Storage shall not be allowed in the outermost shipping carton. The building shall be kept in good repair, clean, sanitary and safe at all times.

(m) The hospital shall appoint a housekeeping supervisor who is qualified for the position by education, training and experience. The housekeeping supervisor shall be responsible for:

(Rule 1200-8-1-.06, continued)

1. Organizing and coordinating the hospital's housekeeping service;

2. Acquiring and storing sufficient housekeeping supplies and equipment for hospital maintenance;

3. Assuring the clean and sanitary condition of the hospital to provide a safe and hygienic environment for patients and staff. Cleaning shall be accomplished in accordance with the infection control rules and regulations herein and hospital policy; and

4. Verifying regular continuing education and competency for basic housekeeping principles.

(n) Laundry facilities located in the hospital shall:

1. Be equipped with an area for receiving, processing, storing and distributing clean linen;

2. Be located in an area that does not require transportation for storage of soiled or contaminated linen through food preparation, storage or dining areas;

3. Provide space for storage of clean linen within nursing units and for bulk storage within clean areas of the hospital. Linen may not be stored in cardboard containers or other containers which offer housing for bugs; and,

4. Provide carts, bags or other acceptable containers appropriately marked to identify those used for soiled linen and those used for clean linen to prevent dual utilization of the equipment and cross contamination.

(o) The hospital shall appoint a laundry service supervisor who is qualified for the position by education, training and experience. The laundry service supervisor shall be responsible for:

1. Establishing a laundry service, either within the hospital or by contract, that provides the hospital with sufficient clean, sanitary linen at all times;

2. Knowing and enforcing infection control rules and regulations for the laundry service;

3. Assuring the collection, packaging, transportation and storage of soiled, contaminated, and clean linen is in accordance with all applicable infection control rules, regulations and procedures;

4. Assuring that a contract laundry service complies with all applicable infection control rules, regulations and procedures; and,

5. Conducting periodic inspections of any contract laundry facility.

(p) The physical environment of the facility shall be maintained in a safe, clean and sanitary manner.

1. Any condition on the hospital site conducive to the harboring or breeding of insects, rodents or other vermin shall be prohibited. Chemical substances of a poisonous nature used to control or eliminate vermin shall be properly identified. Such substances shall not be stored with or near food or medications.

2. Cats, dogs or other animals shall not be allowed in any part of the hospital except for specially trained animals for the handicapped and except as addressed by facility policy for pet therapy programs. The facility shall designate in its policies and procedures those

(Rule 1200-8-1-.06, continued)

areas where animals will be excluded. The areas designated shall be determined based upon an assessment of the facility performed by medically trained personnel.

3. A bed complete with mattress and pillow shall be provided. In addition, patient units shall be provided with at least one chair, a bedside table, an over bed tray and adequate storage space for toilet articles, clothing and personal belongings.

4. Individual wash cloths, towels and bed linens must be provided for each patient. Linen shall not be interchanged from patient to patient until it has been properly laundered.

5. Bath basin water service, emesis basin, bedpan and urinal shall be individually provided.

6. Water pitchers, glasses, thermometers, emesis basins, douche apparatus, enema apparatus, urinals, mouthwash cups, bedpans and similar items of equipment coming into intimate contact with patients shall be disinfected or sterilized after each use unless individual equipment for each is provided and then sterilized or disinfected between patients and as often as necessary to maintain them in a clean and sanitary condition. Single use, patient disposable items are acceptable but shall not be reused.

(4) Nursing Services.

(a) The hospital must have an organized nursing service that provides twenty-four (24) hour nursing services furnished or supervised by a registered nurse, and have a licensed practical nurse or registered nurse on duty at all times.

(b) The hospital must have a well-organized service with a plan of administrative authority and delineation of responsibilities for patient care. The chief nursing officer must be a licensed registered nurse who is responsible for the operation of the service, including determining the types and numbers of nursing personnel and staff necessary to provide nursing care for all areas of the hospital.

(c) The nursing service must have adequate numbers of licensed registered nurses, licensed practical nurses, and other personnel to provide nursing care to all patients as needed. There must be supervisory and staff personnel for each department or nursing unit to ensure, when needed, the immediate availability of a registered nurse for bedside care of any patient.

(d) There must be a procedure to ensure that hospital nursing personnel for whom licensure is required have valid and current licenses.

(e) A registered nurse must assess, supervise and evaluate the nursing care for each patient.

(f) The hospital must ensure that an appropriate individualized plan of care is available for each patient.

(g) A registered nurse must assign the nursing care of each patient to other nursing personnel in accordance with the patient's needs and the specialized qualifications and competence of the nursing staff available. All nursing personnel assigned to special care units shall have specialized training and a program in-service and continuing education commensurate with the duties and responsibilities of the individual. All training shall be documented for each individual so employed, along with documentation of annual competency skills.

(h) A registered nurse may make the actual determination and pronouncement of death under the following circumstances:

1. the deceased was a patient at a hospital as defined by T.C.A. §68-11-201(27);

2. death was anticipated, and the attending physician has agreed in writing to sign the death certificate. Such agreement by the attending physician must be present with the deceased at the place of death;

3. the nurse is licensed by the state; and

4. the nurse is employed by the hospital providing services to the deceased.

(i) Non-employee licensed nurses who are working in the hospital must adhere to the policies and procedures of the hospital. The chief nursing officer must provide for the adequate supervision and evaluation of the clinical activities of non-employee nursing personnel which occur within the responsibility of the nursing service. Annual competency and skill documentation must be demonstrated on these individuals just as employees, if they perform clinical activities.

(j) All drugs, devices and related materials must be administered by, or under the supervision of, nursing or other personnel in accordance with federal and state laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.

(k) All orders for drugs, devices and related materials must be in writing and signed by the practitioner or practitioners responsible for the care of the patient. Electronic and computer-generated records and signature entries are acceptable. When telephone or oral orders must be used, they must be:

1. Accepted only by personnel that are authorized to do so by the medical staff policies and procedures, consistent with federal and state law; and

2. Signed or initialed by the prescribing practitioner according to hospital policy.

(l) Blood transfusions and intravenous medications must be administered in accordance with state law and approved medical staff policies and procedures.

(m) There must be a hospital procedure for reporting transfusion reactions, adverse drug reactions, and errors in administration of drugs.

(5) Medical Records.

(a) The hospital shall comply with the Tennessee Medical Records Act, T.C.A. §68-11-301, et seq. A hospital shall transfer copies of patient medical records in a timely manner to requesting practitioners and facilities.

(b) The hospital must have a medical record service that has administrative responsibility for medical records. The service shall be supervised by a Registered Record Administrator (RRA), an Accredited Record Technician, or a person qualified by work experience. A medical record must be maintained for every individual evaluated or treated in the hospital.

(c) The organization of the medical record service must be appropriate to the scope and complexity of the services performed. The hospital must employ adequate personnel to ensure prompt completion, filing and retrieval of records.

(d) The hospital must maintain a medical record for each inpatient and outpatient. Medical records must be accurate, promptly completed, properly filed and retained, and accessible. The hospital must use a system of author identification and record maintenance that ensures the integrity of the authentication and protects the security of all record entries.

(Rule 1200-8-1-.06, continued)

(e) All medical records, either written, electronic, graphic or otherwise acceptable form, must be retained in their original or legally reproduced form for a minimum period of at least ten (10) years, or for the period of minority plus one year for newborns, after which such records may be destroyed. Records destruction shall be accomplished by burning, shredding or other effective method in keeping with the confidential nature of its contents. The destruction of records must be made in the ordinary course of business, must be documented and in accordance with the hospital's policies and procedures, and no record may be destroyed on an individual basis.

(f) When a hospital closes with no plans of reopening, an authorized representative of the hospital may request final storage or disposition of the hospital's medical records by the department. Upon transfer to the department, the hospital relinquishes all control over final storage of the records in the files of the Tennessee Department of Finance and Administration and the files shall become property of the State of Tennessee.

(g) The hospital must have a system of coding and indexing medical records. The system must allow for timely retrieval by diagnosis and procedure.

(h) The hospital must have a procedure for ensuring the confidentiality of patient records. Information from or copies of records may be released only to authorized individuals, and the hospital must ensure that unauthorized individuals cannot gain access to or alter patient records. Original medical records must be released by the hospital only in accordance with federal and state laws, court orders or subpoenas.

(i) The medical record must contain information to justify admission and continued hospitalization, support the diagnosis, and describe the patient's progress and response to medications and services.

(j) All entries must be legible, complete, dated and authenticated according to hospital policy.

(k) All records must document the following:

1. Evidence of a physical examination, including a health history, performed and/or updated no more than forty-five (45) days prior to admission or within forty-eight (48) hours following admission;

2. Admitting diagnosis;

3. Results of all consultative evaluations of the patient and appropriate findings by clinical and other staff involved in the care of the patient;

4. Documentation of complications, hospital acquired infections, and unfavorable reactions to drugs and anesthesia;

5. Properly executed informed consent forms for procedures and treatments specified by hospital policy, or by federal or state law if applicable, as requiring written patient consent;

6. All practitioners' orders, nursing notes, reports of treatment, medication records, radiology, and laboratory reports, and vital signs and other information necessary to monitor the patient's condition;

7. Discharge summary with outcome of hospitalization, disposition of case and plan for follow-up care; and

8. Final diagnosis with completion of medical records within thirty (30) days following discharge.

(l) Electronic and computer-generated records and signature entries are acceptable.

(6) Pharmaceutical Services.

(a) The hospital must have pharmaceutical services that meet the needs of the patients and are in accordance with the Tennessee Board of Pharmacy statutes and regulations. The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical service.

(b) A full-time, part-time or consulting pharmacist must be responsible for developing, supervising and coordinating all the activities of the pharmacy services.

(c) Current and accurate records must be kept of receipt and disposition of all scheduled drugs.

(d) Adverse drug events, both adverse reactions and medication errors, shall be reported according to established guidelines to the hospital performance improvement/risk management program and as appropriate to physicians, the hospital governing body and regulatory agencies.

(e) Abuses and losses of controlled substances must be reported, in accordance with federal and state laws, to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate.

(f) Current reference materials relating to drug interactions and information of drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration must be available to the professional staff in the pharmacy and in areas where medication is administered.

(g) Any unused portions of prescriptions shall be either turned over to the patient only on a written authorization including directions by the physician, or returned to the pharmacy for proper disposition by the pharmacist.

(h) Whenever patients bring drugs into an institution, such drugs shall not be administered unless they can be identified and ordered to be given by a physician.

(7) Radiologic Services.

(a) The hospital must maintain, or have available, diagnostic radiologic services according to the needs of the patients. If therapeutic services are also provided, they, as well as the diagnostic services, must meet professionally approved standards for safety and personnel qualifications.

(b) The radiologic services must be free from hazards for patients and personnel.

(c) Patients, employees and the general public shall be provided protection from radiation in accordance with "State Regulations for Protection Against Radiation". All radiation producing equipment shall be registered and all radioactive material shall be licensed by the Division of Radiological Health of the Tennessee Department of Environment and Conservation.

(d) Periodic inspections of equipment must be made and hazards identified must be promptly corrected.

(Rule 1200-8-1-.06, continued)

(e) Radiologic services must be provided only on the order of practitioners with clinical privileges or of other practitioners authorized by the medical staff and the governing body to order the services.

(f) X-ray personnel shall be qualified by education, training and experience for the type of service rendered.

(g) All x-ray equipment must be registered with the Tennessee Department of Environment and Conservation, Division of Radiological Health.

(h) X-rays shall be retained for four (4) years and may be retired thereafter provided that a signed interpretation by a radiologist is maintained in the patient's record under T.C.A. § 68-11-305.

(i) Patients must not be left unattended in pre and post radiology areas.

(8) Laboratory Services.

(a) The hospital must maintain, or have available, either directly or through a contractual agreement, adequate laboratory services to meet the needs of its patients. The hospital must ensure that all laboratory services provided to its patients are performed in a facility licensed in accordance with the Tennessee Medical Laboratory Act. All technical laboratory staff shall be licensed in accordance with the TMLA and shall be qualified by education, training and experience for the type of services rendered.

(b) Emergency laboratory services must be available 24 hours a day.

(c) A written description of services provided must be available to the medical staff.

(d) The laboratory must make provision for proper receipt and reporting of tissue specimens.

(e) The medical staff and a pathologist must determine which tissue specimens require a macroscopic (gross) examination and which require both macroscopic and microscopic examination.

(f) Laboratory services must be provided in keeping with services rendered by the hospital. This shall include suitable arrangements for blood and plasma at all times. Written policies and procedures shall be developed in concert with the Standards of American Association of Blood Banks. Documentation and record keeping shall be maintained for tracking and performance monitoring.

(9) Food and Dietetic Services.

(a) The hospital must have organized dietary services that are directed and staffed by adequate qualified personnel. A hospital may contract with an outside food management company if the company has a dietitian who serves the hospital on a full-time, part-time, or consultant basis, and if the company maintains at least the minimum standards specified in this section and provides for constant liaison with the hospital medical staff for recommendations on dietetic policies affecting patient treatment. If an outside contract is utilized for management of its dietary services, the hospital shall designate a full-time employee to be responsible for the overall management of the services.

(b) The hospital must designate a person to serve as the food and dietetic services director with responsibility for the daily management of the dietary services. The food and dietetic services director shall be:

(Rule 1200-8-1-.06, continued)

1. A dietitian; or

2. A graduate of a dietetic technician or dietetic assistant training program, correspondence or classroom, approved by the American Dietetic Association; or

3. A graduate of a state-approved course that provided ninety (90) or more hours of classroom instruction in food service supervision and has experience as a food service supervisor in a health care institution with consultation from a qualified dietitian.

(c) There must be a qualified dietitian, full time, part-time, or on a consultant basis who is responsible for the development and implementation of a nutrition care process to meet the needs of patients for health maintenance, disease prevention and, when necessary, medical nutrition therapy to treat an illness, injury or condition. Medical nutrition therapy includes assessment of the nutritional status of the patient and treatment through diet therapy, counseling and/or use of specialized nutrition supplements.

(d) There must be sufficient administrative and technical personnel competent in their respective duties.

(e) Menus must meet the needs of the patients.

1. Therapeutic diets must be prescribed by the practitioner or practitioners responsible for the care of the patients.

2. Nutritional needs must be met in accordance with recognized dietary practices and in accordance with orders of the practitioners or practitioners responsible for the care of the patients.

3. A current therapeutic diet manual approved by the dietitian and medical staff must be readily available to all medical, nursing, and food service personnel.

(f) Education programs, including orientation, on-the-job training, inservice education, and continuing education programs shall be offered to dietetic services personnel on a regular basis. Programs shall include instruction in personal hygiene, proper inspection, handling, preparation and serving of food and equipment.

(g) A minimum of three (3) meals in each twenty-four (24) hour period shall be served. A supplemental night meal shall be served if more than fourteen (14) hours lapse between supper and breakfast. Additional nourishment shall be provided to patients with special dietary needs.

(h) All food shall be from sources approved or considered satisfactory by the department and shall be clean, wholesome, free from spoilage, free from adulteration and misbranding and safe for human consumption. No food which has been processed in a place other than a commercial food processing establishment shall be used.

(i) Food shall be protected from sources of contamination whether in storage or while being prepared, served and/or transported. Perishable foods shall be stored at such temperatures as to prevent spoilage. Potentially hazardous foods shall be maintained at safe temperatures as defined in the current “U.S. Public Health Service Food Service Sanitation Manual”.

(j) Written policies and procedures shall be followed concerning the scope of food services in accordance with the current edition of the "U.S. Public Health Service Recommended Ordinance and Code Regulating Eating and Drinking Establishments" and the current “U.S. Public Health Service Sanitation Manual” should be used as a guide to food sanitation.

(Rule 1200-8-1-.06, continued)

(10) Critical Access Hospital.

(a) Every patient shall be under the care of a physician or under the care of a mid-level practitioner supervised by a physician.

(b) Whenever a patient is admitted to the facility by a mid-level practitioner, the supervising physician shall be notified of that fact, by phone or otherwise, and within 24 hours the supervising physician shall examine the patient or before discharge if discharged within 24 hours, and a plan of care shall be placed in the patient's chart, unless the patient is transferred to a higher level of care within 24 hours.

(c) A physician, a mid-level practitioner or a registered nurse shall be on duty and physically available in the facility when there are inpatients.

(d) A physician on staff shall:

1. Provide medical direction to the facility's health care activities and consultation for non-physician health care providers.

2. In conjunction with the mid-level practitioner staff members, participate in developing, executing, and periodically reviewing the facility's written policies and the services provided to patients.

3. Review and sign the records of each patient admitted and treated by a practitioner no later than fifteen (15) days after the patient's discharge from the facility.

4. Provide health care services to the patients in the facility, whenever needed and requested.

5. Prepare guidelines for the medical management of health problems, including conditions requiring medical consultation and/or patient referral.

6. At intervals no more than two (2) weeks apart, be physically present in the facility for a sufficient time to provide medical direction, medical care services, and staff consultation as required.

7. When not physically present in the facility, either be available through direct telecommunication for consultation and assistance with medical emergencies and patient referral, or ensure that another physician is available for this purpose.

8. The physical site visit for a given two week period is not required if, during that period, no inpatients have been treated in the facility.

(e) A mid-level practitioner on staff shall:

1. Participate in the development, execution, and periodic review of the guidelines and written policies governing treatment in the facility.

2. Participate with a physician in a review of each patient's health records.

3. Provide health care services to patients according to the facility's policies.

4. Arrange for or refer patients to needed services that are not provided at the facility.

(Rule 1200-8-1-.06, continued)

5. Assure that adequate patient health records are maintained and transferred as necessary when a patient is referred.

(f) The Critical Access Hospital, at a minimum, shall provide basic laboratory services essential to the immediate diagnosis and treatment of patients, including:

1. Chemical examinations of urine stick or tablet methods, or both (including urine ketoses);

2. Microscopic examinations of urine sediment;

3. Hemoglobin or hematocrit;

4. Blood sugar;

5. Gram stain;

6. Examination of stool specimens for occult blood;

7. Pregnancy test;

8. Primary culturing for transmittal to a CLIA certified laboratory;

9. Sediment rate; and,

10. CBC.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-3-511, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.* ***Administrative History:*** *Original rule filed March 18, 2000; effective May 30, 2000. Amendment filed December 2, 2003; effective February 15, 2004. Amendment filed May 24, 2004; effective August 7, 2004. Amendment filed September 6, 2005; effective November 20, 2005. Amendment filed July 18, 2007; effective October 1, 2007.*

1200-8-1-.07 OPTIONAL HOSPITAL SERVICES.

(1) Surgical Services.

(a) If the hospital provides surgical services, the services must be well organized and provided in accordance with acceptable standards of practice. If outpatient surgical services are offered, the services must be consistent in quality with inpatient care in accordance with the complexity of services offered.

(b) The organization of the surgical services must be appropriate to the scope of the services offered.

(c) The operating rooms must be supervised by an experienced registered nurse or a doctor of medicine or osteopathy.

(d) Licensed practical nurses (LPNs) and surgical technologists (operating room technicians) may serve as “scrub nurses” under the supervision of a registered nurse.

(e) Qualified registered nurses may perform circulating duties in the operating room. In accordance with applicable state laws and approved medical staff policies and procedures, LPNs and surgical technologists may assist in circulatory duties under the supervision of a qualified registered nurse who is immediately available to respond to emergencies.

(Rule 1200-8-1-.07, continued)

(f) Surgical privileges must be delineated for all practitioners performing surgery in accordance with the competencies of each practitioner. The surgical service must maintain a roster of practitioners specifying the surgical privileges of each practitioner.

(g) Surgical services must be consistent with needs and resources. Policies covering surgical care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care.

(h) Surgical technologists must:

1. Hold current national certification established by the Liaison Council on Certification for the Surgical Technologist (LCC-ST); or

2. Have completed a program for surgical technology accredited by the Commission on Accreditation of Allied Health Education Programs (CAAHEP); or

3. Have completed an appropriate training program for surgical technologists in the armed forces or at a CAAHEP accredited hospital or CAAHEP accredited ambulatory surgical treatment center; or

4. Successfully complete the surgical technologists LCC-ST certifying exam; or

5. Provide sufficient evidence that, prior to July 1, 2006, the person began training to be a surgical technologist, or was at any time employed as a surgical technologist for not less than eighteen (18) months in a hospital, medical office, surgery center, or school.

(i) A hospital can petition the director of health care facilities of the department for a waiver from the provisions of 1200-8-1-.07(1)(h) if they are unable to employ a sufficient number of surgical technologists who meet the requirements. The facility shall demonstrate to the director that a diligent and thorough effort has been made to employ surgical technologist who meet the requirements. The director shall refuse to grant a waiver upon finding that a diligent and thorough effort has not been made. A waiver shall exempt a facility from meeting the requirements for not more than nine (9) months. Additional waivers may be granted, but all exemptions greater than twelve (12) months shall be approved by the Board for Licensing Health Care Facilities.

(j) Surgical technologists shall demonstrate continued competence in order to perform their professional duties in surgical technology. The employer shall maintain evidence of the continued competence of such individuals. Continued competence activities may include but are not limited to continuing education, in-service training, or certification renewal.

(k) There must be a complete history and physical work-up in the chart of every patient prior to surgery, except in emergencies. If the history has been dictated, but not yet recorded in the patient's chart, there must be a statement to that effect and an admission note in the chart by the practitioner who admitted the patient.

(l) Properly executed informed consent, advance directive, and organ donation forms, when applicable, must be in the patient's chart before surgery, except in emergencies.

(m) The following equipment must be available to the operating room suites:

1. Call-in system;

2. Cardiac monitor;

(Rule 1200-8-1-.07, continued)

3. Resuscitator;

4. Defibrillator;

5. Aspirator; and

6. Tracheotomy set.

(n) There must be adequate provisions for immediate pre and post-operative care.

(o) The operating room register must be complete and up-to-date.

(p) An operative report describing techniques, findings, and tissues removed or altered must be written or dictated immediately following surgery and signed by the surgeon.

(2) Anesthesia Services.

(a) If the hospital furnishes anesthesia services, they must be provided in a well organized manner under the direction of a qualified doctor of medicine or osteopathy. The service is responsible for all anesthesia administered in the hospital.

(b) The organization of anesthesia services must be appropriate to the scope of the services offered. Anesthesia must be administered only by:

1. A qualified anesthesiologist;

2. A doctor of medicine or osteopathy (other than an anesthesiologist);

3. A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law;

4. A certified registered nurse anesthetist (CRNA); or

5. A graduate registered nurse anesthetist under the supervision of an anesthesiologist who is immediately available if needed.

(c) Anesthesia services must be consistent with needs and resources. Policies on anesthesia procedures must include the delineation of pre-anesthesia and post-anesthesia responsibilities. The policies must ensure that the following are provided for each patient:

1. A pre-anesthesia evaluation or evaluation update conducted within forty-eight (48) hours prior to surgery by an individual qualified to administer anesthesia;

2. An intraoperative anesthesia record;

3. For each inpatient, a written post-anesthesia follow-up report prepared within forty-eight (48) hours following surgery by an individual qualified to administer anesthesia or by the person who administered the anesthesia and submits the report by telephone; and

4. For each outpatient, a post-anesthesia evaluation of anesthesia recovery prepared in accordance with policies and procedures approved by the medical staff.

(3) Nuclear Medicine Services.

(Rule 1200-8-1-.07, continued)

(a) If the hospital provides nuclear medicine services, those services must meet the needs of the patients in accordance with acceptable standards of practice.

(b) The organization of the nuclear medicine service must be appropriate to the scope and complexity of the services offered.

(c) There must be a director who is a doctor of medicine or osteopathy qualified in nuclear medicine.

(d) The qualifications, training, functions, and responsibilities of nuclear medicine personnel must be specified by the service director and approved by the medical staff.

(e) Radioactive materials must be prepared, labeled, used, transported, stored, and disposed of in accordance with acceptable standards of practice.

(f) In-house preparation of radiopharmaceuticals is by, or under, the direct supervision of an appropriately trained registered pharmacist or a doctor of medicine or osteopathy.

(g) If laboratory tests are performed in the nuclear medicine service, the service must meet the applicable requirements for laboratory services as specified in TCA § 68-29-101, et seq.

(h) Equipment and supplies must be appropriate for the types of nuclear medicine services offered and must be maintained for safe and efficient performance. The equipment must be:

1. Maintained in safe operating condition; and,

2. Inspected, tested, and calibrated at least annually by qualified personnel.

(i) The hospital must maintain signed and dated reports of nuclear medicine interpretations, consultations, and procedures. Copies of nuclear medicine reports must be maintained for at least ten (10) years.

(j) The practitioner approved by the medical staff to interpret diagnostic procedures must sign and date the interpretation of these tests.

(k) The hospital must maintain records of the receipt and disposition of radiopharmaceuticals.

(l) Nuclear medicine services must be ordered only by a practitioner whose scope of federal or state licensure and whose defined staff privileges allow such referrals.

(m) Patients are not left unattended in pre and post procedure areas.

(4) Outpatient Services.

(a) If the hospital provides outpatient services, the services must meet the needs of the patients in accordance with acceptable standards of practice.

(b) Outpatient services must be appropriately organized and integrated with inpatient services.

(c) The hospital must have appropriate professional and non-professional personnel available to provide outpatient services.

(d) Patient's rights, including a phone number to call regarding questions or concerns, shall be made readily available to outpatients.

(Rule 1200-8-1-.07, continued)

(e) Outpatient laboratory testing in Tennessee hospitals may be ordered by the following:

1. Any licensed Tennessee practitioner who is authorized to do so by T.C.A. § 68-29-121;

2. Any out of state practitioner who has a Tennessee telemedicine license issued pursuant to rule 0880-2-.16; or

3. Any duly licensed out of state health care professional as listed in T.C.A. § 68-29-121 who is authorized by his or her state board to order outpatient laboratory testing in hospitals for individuals with whom that practitioner has an existing face-to-face patient relationship as outlined in rule 0880-2-.14(7)(a)1., 2., and 3.

(f) Outpatient diagnostic testing in Tennessee hospitals may be ordered by the following:

1. Any Tennessee practitioner licensed under Title 63 who is authorized to do so by his or her practice act;

2. Any out of state practitioner who has a Tennessee telemedicine license issued pursuant to rule 0880-2-.16; or

3. Any duly licensed out of state health care professional who is authorized by his or her state board to order outpatient diagnostic testing in hospitals for individuals with whom that practitioner has an existing face-to-face patient relationship as outlined in rule 0880-2-.14(7) (a)1., 2., and 3.

(5) Emergency Services.

(a) Hospitals that elect to provide surgical services, other than in a separately licensed Ambulatory Surgical Treatment Center, must maintain and operate an emergency room.

(b) If emergency services are provided, the hospital must meet the emergency needs of patients in accordance with acceptable standards of practice. Each hospital must have a policy which assures that all patients who present to the emergency department, are screened/triaged to determine if a medical emergency exists and stabilized when a medical emergency does exist. A hospital may deny access to patients when it is on diversionary status only because it does not have the staff or facilities in the emergency department to accept any additional emergency patients at that time. If an ambulance disregards the hospital's instructions and brings an individual on to the hospital grounds, the individual has arrived on hospital property and cannot be denied access to hospital services. Hospital property, for the purpose of this subparagraph, is considered to be:

1. The hospital's physical geographic boundaries; or

2. Ambulances owned and operated by the hospital, whenever in operation, whether or not on hospital grounds.

(c) A hospital may not delay provision of an appropriate medical screening examination in order to inquire about the individual's method of payment or insurance status.

(d) If emergency services are provided at the hospital:

1. The services must be organized under the direction of a qualified member of the medical staff;

2. The services must be integrated with other departments of the hospital; and

3. The policies and procedures governing medical care provided in the emergency service or department are established by and are a continuing responsibility of the medical staff. These policies and procedures must define how the hospital will assess, stabilize, treat and/or transfer patients.

(e) There must be adequate medical and nursing personnel qualified in emergency care to meet the written emergency procedures and needs anticipated by the facility.

(f) There shall be a sufficient number of emergency rooms and adequate equipment and supplies to accommodate the caseload of the emergency services.

(g) The entrance to the emergency department shall be clearly marked.

(h) Legend drugs in emergency rooms shall be stored in locked cabinets, except as otherwise provided for emergency drugs by the written policies and procedures of the hospital. Discharge medications may be dispensed to out-patients upon written physician orders provided that they have been packaged in containers by the pharmacist in amounts not to exceed twelve (12) hours dosage and labeled in accordance with Pharmacy Board rules.

(i) Emergency Room medical records shall include the following:

1. Identification data;

2. Information concerning the time of arrival, means and by whom transported;

3. Pertinent history of the injury or illness to include chief complaint and onset of injuries or illness;

4. Significant physical findings;

5. Description of laboratory, x-ray and EKG findings;

6. Treatment rendered;

7. Condition of the patient on discharge or transfer;

8. Diagnosis on discharge;

9. Instructions given to the patient or his family; and

10. A control register listing chronologically the patient visits to the emergency room. The record shall contain at least the patient's name, date and time of arrival and record number. The name of those dead on arrival shall be entered in the register.

(j) Emergency patients and their families are made aware of their rights, including a number to call regarding concerns or questions.

(6) Rehabilitation Services.

(a) If the hospital provides rehabilitation, physical therapy, occupational therapy, audiology, or speech pathology services, the services must be organized and staffed to ensure the health and safety of patients. These disciplines should document their contribution to the plan for patient care.

(Rule 1200-8-1-.07, continued)

(b) The organization of the service must be appropriate to the scope of the services offered.

(c) The director of the service must have the necessary knowledge, experience, and capabilities to properly supervise and administer the services.

(d) Physical therapy, occupational therapy, speech therapy, or audiology services, if provided, must be provided by staff who meet the qualifications specified by hospital policy, consistent with state law.

(e) Services must be furnished in accordance with a written plan of treatment. Services must be given in accordance with orders of practitioners who are authorized by the medical staff to order the services and the orders must be incorporated in the patient's record.

(7) Obstetrical Services.

(a) If a hospital provides obstetrical services it shall have space, facilities, equipment and qualified personnel to assure appropriate treatment of all maternity patients and newborns.

(b) The hospital must have written policies and procedures governing medical care provided in the obstetrical service which are established by and are a continuing responsibility of the medical staff.

(c) Provisions must be made for care of the patient during labor and delivery, either in the patient's room or in a designated room.

(d) Designated delivery rooms shall be segregated from patient areas and be located so as not to be used as a passageway between or subject to contamination from other parts of the hospital.

(e) A delivery record shall be kept that must indicate:

1. The name of the patient;

2. Her maiden name;

3. Date of delivery;

4. Sex of infant;

5. Name of physician;

6. Names of persons assisting;

7. What complications, if any, occurred;

8. Type of anesthesia used;

9. Name of person administering anesthesia; and

10. Other persons present.

(8) Pediatric Services.

(a) If the hospital provides pediatric services, it shall provide appropriate pediatric equipment and supplies.

(Rule 1200-8-1-.07, continued)

(b) Pediatric services must be appropriate to the scope and complexity of the services offered and must meet the needs of the patients in accordance with acceptable standards of practice.

(c) The hospital must have appropriate professional and non-professional personnel available to provide pediatric services.

(9) Respiratory Care Services.

(a) If the hospital provides respiratory care services, the hospital must meet the needs of the patients in accordance with acceptable standards of practice.

(b) The organization of the respiratory care services must be appropriate to the scope and complexity of the services offered.

(c) There must be a director of respiratory care services who is a doctor of medicine or osteopathy with the knowledge, experience, and capabilities to supervise and administer the service properly.

(d) There must be adequate numbers of certified respiratory therapists, certified respiratory therapy technicians, and other personnel who meet the qualifications specified by the medical staff, consistent with state law.

(e) Services must be delivered in accordance with medical staff directives.

(f) Personnel qualified to perform specific procedures and the amount of supervision required for personnel to carry out specific procedures must be designated in writing.

(g) If blood gases or other laboratory tests are performed in the respiratory care unit, the unit must meet the applicable requirements for clinical laboratory services specified in the Tennessee Medical Laboratory Act.

(10) Social Work Services.

(a) If the hospital provides social work services, the services must be available to the patient, the patient's family and other persons significant to the patient, in order to facilitate adjustment of these individuals to the impact of illness and to promote maximum benefits from the health care services provided.

(b) Social work services shall include psychosocial assessment, counseling, coordination of discharge planning, community liaison services, financial assistance and consultation.

(c) Social work services shall be provided by personnel who satisfy applicable accreditation standards and who are in compliance with Tennessee State Law governing social work practices. Social work personnel employed by the hospital prior to the effective date of these regulations shall be deemed to meet this requirement.

(d) Facilities for social work services shall be readily accessible and shall permit privacy for interviews and counseling.

(11) Psychiatric Services.

(a) If a hospital provides psychiatric services, a psychiatric unit devoted exclusively for the care and treatment of psychiatric patients and professional personnel qualified in the diagnosis and treatment of patients with psychiatric illnesses shall be provided. Adequate protection shall be provided for patients and the staff against any physical injury resulting from a patient becoming

(Rule 1200-8-1-.07, continued)

violent. A psychiatric unit shall meet the requirements as needed to care for patients admitted, either through direct care or by contractual arrangements.

(b) A hospital licensed by the Department of Health as a satellite hospital whose primary purpose is the provision of mental health or mental retardation services, must verify to the Department that Standards of the Department of Mental Health and Mental Retardation are satisfied.

(12) Alcohol and Drug Services.

(a) If a hospital provides alcohol and drug services, the service shall be devoted exclusively to the care and treatment of alcohol and drug dependent patients and have on staff physicians and other professional personnel qualified in the diagnosis and treatment of alcoholism and drug addiction.

(b) Adequate protection shall be provided for the patients and staff against any physical injury resulting from a patient becoming disturbed or violent. Alcohol and drug services shall meet the requirements as needed to care for patients admitted, either through direct care or by contractual arrangements.

(13) Perinatal and/or Neonatal Care Services. Any hospital providing perinatal and/or neonatal care services shall comply with the Tennessee Perinatal Care System Guidelines for Regionalization, Hospital Care Levels, Staffing and Facilities developed by the Tennessee Department of Health's Perinatal Advisory Committee, June 1997 including amendments as necessary.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-209, 68-57-101, 68-57-102, and 68-57-104.* ***Administrative History:*** *Original rule filed March 18, 2000; effective May 30, 2000. Amendment filed April 17, 2000; effective July 1, 2000. Amendment filed June 12, 2003; effective August 26, 2003. Amendment filed July 27, 2005; effective October 10, 2005. Amendment filed February 23, 2006; effective May 9, 2006. Amendment filed February 23, 2007; effective May 9, 2007.*

1200-8-1-.08 BUILDING STANDARDS.

(1) The hospital must be constructed, arranged, and maintained to ensure the safety of the patient.

(2) The condition of the physical plant and the overall hospital environment must be developed and maintained in such a manner that the safety and well-being of patients are assured.

(3) No new hospital shall hereafter be constructed, nor shall major alterations be made to existing hospitals, or change in hospital type be made without the prior written approval of the department, and unless in accordance with plans and specifications approved in advance by the department. Before any new hospital is licensed or before any alteration or expansion of a licensed hospital can be approved, the applicant must furnish two (2) complete sets of plans and specifications to the department, together with fees and other information as required. Plans and specifications for new construction and major renovations, other than minor alterations not affecting fire and life safety or functional issues, shall be prepared by or under the direction of a licensed architect and/or a qualified licensed engineer.

(4) After the application and licensure fees have been submitted, the building construction plans must be submitted to the department. All new facilities shall conform to the current addition of the Standard Building Code, the National Fire Protection Code (NFPA), the National Electrical Code, the AIA Guidelines for Design and Construction of Hospital and Health Care Facilities, and the U.S Public Health Service Food Code as adopted by the Board for Licensing Health Care Facilities. When referring to height, area or construction type, the Standard Building Code shall prevail. All new and existing facilities are subject to the requirements of the Americans with Disabilities Act (A.D.A.).

(Rule 1200-8-1-.08, continued)

Where there are conflicts between requirements in the above listed codes and regulations and provisions of this chapter, the most restrictive shall apply.

(5) The codes in effect at the time of submittal of plans and specifications, as defined by these regulations shall be the codes to be used throughout the project.

(6) Review of plans and specifications shall be acknowledged in writing with copies sent to the architect and the owner, manager or other executive of the institution. The distribution of such review may be modified at the discretion of the department.

(7) All construction shall be executed in accordance with the approved plans and specifications.

(8) All new construction and renovations to hospitals, other than minor alterations not affecting fire and life safety or functional issues, shall be performed in accordance with the specific requirements of these regulations governing new construction in hospitals, including the submission of phased construction plans and the final drawings and the specifications to each.

(9) In the event submitted materials do not appear to satisfactorily comply with 1200-8-1-.08 (4) the department shall furnish a letter to the party submitting the plans which shall list the particular items in question and request further explanation and/or confirmation of necessary modifications.

(10) Notice of satisfactory review from the department constitutes compliance with this requirement if construction begins within one hundred eighty (180) days of the date of such notice. This approval shall in no way permit and/or authorize any omission or deviation from the requirements of any restrictions, laws, regulations, ordinances, codes or rules of any responsible agency.

(11) Final working drawings and specifications shall be accurately dimensioned and include all necessary explanatory notes, schedules and legends. The working drawings and specifications shall be complete and adequate for contract purposes.

(12) Prior to final inspection, a CD Rom disc, in TIF or DMG format, of the final approved plans including all shop drawings, sprinkler, calculations, hood and duct, addenda, specifications, etc., shall be submitted to the department.

(13) Detailed plans shall be drawn to a scale of at least one-eighth inch equals one foot (1/8" = 1'), and shall show the general arrangement of the building, the intended purpose and the fixed equipment in each room, with such additional information as the department may require. These plans shall be prepared by an architect or engineer licensed to practice in the State of Tennessee. The plans shall contain a certificate signed by the architect or engineer that to the best of his or her knowledge or belief the plans conform to all applicable codes.

(a) Two (2) sets of plans shall be forwarded to the appropriate section of the department for review. After receipt of approval of phased construction plans, the owner may proceed with site grading and foundation work prior to receipt of approval of final plans and specifications with the understanding that such work is at the owner's risk and without assurance that final approval of final plans and specifications shall be granted. Final plans and specifications shall be submitted for review and approval. Final approval must be received before proceeding beyond foundation work.

(b) Review of plans does not eliminate responsibility of owner and/or architect to comply with all rules and regulations.

(14) Specifications shall supplement all drawings. They shall describe the characteristics of all materials, products and devices, unless fully described and indicated on the drawings. Specification copies should be bound in an 8½ x 11 inch folder.

(Rule 1200-8-1-.08, continued)

(15) Drawings and specifications shall be prepared for each of the following branches of work: Architectural, Structural, Mechanical, Electrical and Sprinkler.

(16) Architectural drawings shall include:

(a) Plot plan(s) showing property lines, finish grade, location of existing and proposed structures, roadways, walks, utilities and parking areas;

(b) Floor plan(s) showing scale drawings of typical and special rooms, indicating all fixed and movable equipment and major items of furniture;

(c) Separate life safety plans showing the compartment(s), all means of egress and exit markings, exits and travel distances, dimensions of compartments and calculation and tabulation of exit units. All fire and smoke walls must be identified;

(d) The elevation of each facade;

(e) The typical sections throughout the building;

(f) The schedule of finishes;

(g) The schedule of doors and windows;

(h) Roof plans;

(i) Details and dimensions of elevator shaft(s), car platform(s), doors, pit(s), equipment in the machine room, and the rates of car travel must be indicated for elevators; and

(j) Code analysis.

(17) Structural drawings shall include:

(a) Plans of foundations, floors, roofs and intermediate levels which show a complete design with sizes, sections and the relative location of the various members;

(b) Schedules of beams, girders and columns; and

(c) Design live load values for wind, roof, floor, stairs, guard, handrails, and seismic.

(18) Mechanical drawings shall include:

(a) Specifications which show the complete heating, ventilating, fire protection, medical gas systems and air conditioning systems;

(b) Water supply, sewerage and HVAC piping systems;

(c) Pressure relationships shall be shown on all floor plans;

(d) Heating, ventilating, HVAC piping, medical gas systems and air conditioning systems with all related piping and auxiliaries to provide a satisfactory installation;

(e) Water supply, sewage and drainage with all lines, risers, catch basins, manholes and cleanouts clearly indicated as to location, size, capacities, etc., and location and dimensions of septic tank and disposal field; and,

(Rule 1200-8-1-.08, continued)

(f) Color coding to show clearly supply, return and exhaust systems.

(19) Electrical drawings shall include:

(a) A certification that all electrical work and equipment is in compliance with all applicable local codes and laws, and that all materials are currently listed by recognized testing laboratories;

(b) All electrical wiring, outlets, riser diagrams, switches, special electrical connections, electrical service entrance with service switches, service feeders and characteristics of the light and power current, and transformers when located within the building;

(c) The electrical system shall comply with applicable codes, and shall include:

1. The nurses call system;

2. The paging system;

3. The fire alarm system; and

4. The emergency power system including automatic services as defined by the codes.

(d) Color coding to show all items on emergency power.

(20) Sprinkler drawings shall include:

(a) Shop drawings, hydraulic calculations, and manufacturer cut sheets;

(b) Site plan showing elevation of fire hydrant to building, test hydrant, and flow data (Data from within a 12 month period); and

(c) Show “Point of Service” where water is used exclusively for fire protection purposes.

(21) No system of water supply, plumbing, sewage, garbage or refuse disposal shall be installed nor shall any existing system be materially altered or extended until complete plans and specifications for the installation, alteration or extension have been submitted to the department and show that all applicable codes have been met and necessary approval has been obtained.

(a) Before the facility is used, the water supply system shall be approved by the Tennessee Department of Environment and Conservation.

(b) Sewage shall be discharged into a municipal system or approved package system where available; otherwise, the sewage shall be treated and disposed of in a manner of operation approved by the Department of Environment and Conservation and shall comply with existing codes, ordinances and regulations which are enforced by cities, counties or other areas of local political jurisdiction.

(22) The following alarms are required and shall be monitored twenty-four (24) hours per day:

(a) Fire alarms;

(b) Generators; and

(c) Medical gas alarms.

(Rule 1200-8-1-.08, continued)

(23) A negative air pressure shall be maintained in the soiled utility area, toilet room, janitor's closet, dishwashing and other such soiled spaces, and a positive air pressure shall be maintained in all clean areas including, but not limited to, clean linen rooms and clean utility rooms.

(24) Rooms and areas containing radiation producing machines or radioactive material must have primary and/or secondary barriers to assure compliance with Regulations for Protection Against Radiation and security of materials. Radiation material shall be required to be stored and security must be provided in accordance with federal and state regulations to prevent exposure of the material to theft or tampering.

(25) When constructing new facilities or during major renovations to the operating suites, male and female physicians and staff shall have equitable proportional locker facilities including equal equipment, and similar amenities, with equal access to uniforms. In existing facilities the hospital shall strive to have equitable male and female facilities. If physical changes are required, the additional areas shall maintain the flow and divisions in the sterile environments.

(26) Each hospital shall ensure that an emergency keyed lock box is installed next to each bank of functioning elevators located on the main level. Such lock boxes shall be permanently mounted seventy-two inches (72") from the floor to the center of the box, be operable by a universal key no matter where such box is located, and shall contain only fire service keys and drop keys to the appropriate elevators.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-216 and 68-11-261.* ***Administrative History:*** *Original rule filed March 18, 2000; effective May 30, 2000. Amendment filed February 18, 2003; effective May 4, 2003. Repeal and new rule filed September 6, 2005; effective November 20, 2005. Amendment filed February 23, 2007; effective May 9, 2007.*

1200-8-1-.09 LIFE SAFETY.

(1) Any hospital which complies with the required applicable building and fire safety regulations at the time the board adopts new codes or regulations will, so long as such compliance is maintained (either with or without waivers of specific provisions), be considered to be in compliance with the requirements of the new codes or regulations.

(2) The hospital shall provide fire protection by the elimination of fire hazards, by the installation of necessary fire fighting equipment and by the adoption of a written fire control plan. Fire drills shall be held at least quarterly for each work shift for hospital personnel in each separate patient-occupied hospital building. There shall be a written report documenting the evaluation of each drill and the action recommended or taken for any deficiencies found. Records which document and evaluate these drills must be maintained for at least three (3) years. All fires which result in a response by the local fire department shall be reported to the department within seven (7) days. The report shall contain sufficient information to ascertain the nature and location of the fire, its probable cause and any injuries incurred by any person or persons as a result of the fire. Initial reports by the facility may omit the name(s) of patient(s) and parties involved, however, should the department find the identities of such persons to be necessary to an investigation, the facility shall provide such information.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.* ***Administrative History:*** *Original rule filed March 18, 2000; effective May 30, 2000. Amendments filed September 6, 2005; effective November 20, 2005.*

1200-8-1-.10 INFECTIOUS WASTE AND HAZARDOUS WASTE.

(1) Each hospital must develop, maintain and implement written policies and procedures for the definition and handling of its infectious and hazardous wastes. These policies and procedures must comply with the standards of this section and all other applicable state and federal regulations.

(Rule 1200-8-1-.10, continued)

(2) The following waste shall be considered to be infectious waste:

(a) Waste contaminated by patients who are isolated due to communicable disease, as provided in the U.S. Centers for Disease Control "Guidelines for Isolation Precautions in Hospitals";

(b) Cultures and stocks of infectious agents including specimen cultures collected from medical and pathological laboratories, cultures and stocks of infectious agents from research and industrial laboratories, waste from the production of biologicals, discarded live and attenuated vaccines, culture dishes and devices used to transfer, inoculate, and mix cultures;

(c) Waste human blood and blood products such as serum, plasma, and other blood components;

(d) Pathological waste, such as tissues, organs, body parts, and body fluids that are removed during surgery and autopsy;

(e) All discarded sharps (e.g., hypodermic needles, syringes, pasteur pipettes, broken glass, scalpel blades) used in patient care or which have come into contact with infectious agents during use in medical, research, or industrial laboratories;

(f) Contaminated carcasses, body parts, and bedding of animals that were exposed to pathogens in research, in the production of biologicals, or in the in vivo testing of pharmaceuticals; and

(g) Other waste determined to be infectious by the facility in its written policy.

(3) Infectious and hazardous waste must be segregated from other waste at the point of generation (i.e., the point at which the material becomes a waste) within the facility.

(4) Waste must be packaged in a manner that will protect waste handlers and the public from possible injury and disease that may result from exposure to the waste. Such packaging must provide for containment of the waste from the point of generation up to the point of storage, proper treatment or disposal. Packaging must be selected and utilized for the type of waste the package will contain, how the waste will be treated and disposed, and how it will be handled and transported or stored prior to treatment and disposal.

(a) Contaminated sharps must be directly placed in leakproof, rigid, and puncture-resistant containers which must then be tightly sealed;

(b) Whether disposable or reusable, all containers, bags, and boxes used for containment and disposal of infectious waste must be conspicuously identified. Packages containing infectious waste which pose additional hazards (e.g., chemical, radiological) must also be conspicuously identified to clearly indicate those additional hazards;

(c) Reusable containers for infectious waste must be thoroughly disinfected each time they are emptied, unless the surfaces of the containers have been completely protected from contamination by disposable fluid resistant liners or other devices removed with the waste; and

(d) Opaque packaging must be used for pathological waste.

(5) After packaging, waste must be handled and transported by methods ensuring containment and preserving the integrity of the packaging, including the use of secondary containment where necessary.

(a) Infectious waste must not be compacted or ground (i.e., in a mechanical grinder) prior to treatment, except that pathological waste may be ground prior to disposal; and

(b) Plastic bags of infectious waste must be transported by hand.

(6) Waste must be stored in a manner which preserves the integrity of the packaging, inhibits rapid microbial growth and putrefaction, and minimizes the potential of exposure or access by unknowing persons.

(a) Waste must be stored in a manner and location which affords protection from animals, precipitation, wind, and direct sunlight, does not present a safety hazard, does not provide a breeding place or food source for insects or rodents and does not create a nuisance.

(b) Pathological waste must be promptly treated, disposed of, or placed into refrigerated storage.

(c) Outside containers should have a biohazard label conspicuously identified.

(7) In the event of spills, ruptured packaging, or other incidents where there is a loss of containment of waste, the facility must ensure that proper actions are immediately taken to:

(a) Isolate the area from the public and all except essential personnel;

(b) To the extent practicable, repackage all spilled waste and contaminated debris in accordance with the requirements of paragraph (6) of this section;

(c) Sanitize all contaminated equipment and surfaces appropriately. Written policies and procedure must specify how this will be done; and

(d) Complete incident report and maintain copy on file.

(8) Except as provided otherwise in this section a facility must treat or dispose of infectious waste by one or more of the methods specified in this part.

(a) A facility may treat infectious waste in an on-site sterilization or disinfection device, or in an incinerator or a steam sterilizer, which has been designed, constructed, operated and maintained so that infectious waste treated in such a device are rendered non-infectious and is, if applicable, authorized for that purpose pursuant to current rules of the Department of Environment and Conservation. A valid permit or other written evidence of having complied with the Tennessee Air Pollution Control Regulations shall be available for review, if required. Each sterilizing or disinfection cycle must contain appropriate indicators to assure conditions were met for proper sterilization or disinfection of materials included in the cycle, and records kept. Proper operation of such devices must be verified at least monthly, and records of these monthly checks shall be available for review. Waste that contains toxic chemicals that would be volatilized by steam must not be treated in steam sterilizers. Infectious waste that has been rendered to a carbonized or mineralized ash shall be deemed non-infectious. Unless otherwise hazardous and subject to the hazardous waste management requirements of the current rules of the Department of Environment and Conservation, such ash shall be disposable as a (non-hazardous) solid waste under current rules of the Department of Environment and Conservation.

(b) The facility may discharge liquid or semi-liquid infectious waste to the collection sewerage system of a wastewater treatment facility which is subject to a permit pursuant to T.C.A. §69-3-101, et seq., provided that such discharge is in accordance with any applicable terms of that permit and/or any applicable municipal sewer use requirements.

(c) Any health care facility accepting waste from another state must promptly notify the Department of Environment and Conservation, county, and city public health agencies, and must strictly comply with all applicable local, state and federal regulations.

(Rule 1200-8-1-.10, continued)

(9) The facility may have waste transported off-site for storage, treatment, or disposal. Such arrangements must be detailed in a written contract, available for review. If such off-site location is located within Tennessee, the facility must ensure that it has all necessary state and local approvals, and such approvals shall be available for review. If the off-site location is within another state, the facility must notify in writing all public health agencies with jurisdiction that the location is being used for management of the facility's waste. Waste shipped off-site must be packaged in accordance with applicable federal and state requirements. Waste transported to a sanitary landfill in this state must meet the requirements of current rules of the Department of Environment and Conservation.

(10) Human anatomical remains which are transferred to a mortician for cremation or burial shall be exempt from the requirements of this subparagraph. Any other human limbs and recognizable organs must be incinerated or discharged (following grinding) to the sewer.

(11) All garbage, trash and other non-infectious waste shall be stored, transported, and disposed of in a manner that must not permit the transmission of disease, create a nuisance, provide a breeding place for insects and rodents, or constitute a safety hazard. All containers for waste shall be water tight, constructed of easily-cleanable material and shall be kept on elevated platforms.

Authority: *T.C.A. §§4-5-202, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.* ***Administrative History:*** *Original rule filed March 18, 2000; effective May 30, 2000.*

1200-8-1-.11 RECORDS AND REPORTS.

(1) A report listing all births, deaths and reportable fetal deaths which have occurred in the hospital shall be filed with the local registrar in the county where the institution is located or as otherwise directed by the State Registrar. The report shall be filed on the third (3rd) day of the month after the month in which the event occurred on a form or in a format prescribed by the State Registrar. If no birth, death or reportable fetal death occurred in the hospital, the report should be filed to indicate that fact.

(2) A Certificate of Live Birth shall be prepared for each live birth which occurred in the hospital or en route thereto on a form or in a format prescribed by the State Registrar and submitted to the State Registrar within ten (10) days of the birth.

(3) Immediately before or after the birth of a child to an unmarried woman in the facility, an authorized representative of the facility shall provide the mother, and if present, the biological father:

(a) Written information concerning the benefits, rights and responsibilities of establishing paternity for the child, as provided to the hospital by the Tennessee Department of Human Services;

(b) An Acknowledgment of Paternity Form provided by the department; and

(c) The opportunity to complete and submit to the hospital the Acknowledgment Form. The original, signed Acknowledgment of Paternity Form shall be submitted with the original birth certificate as directed by the State Registrar. A duplicate original Acknowledgment of Paternity Form shall be filed with the juvenile court of the county where the mother resides. Copies of the acknowledgment form shall be provided to the mother and the father of the child.

(4) A report of fetal death shall be completed by the hospital for each dead fetus delivered where the fetus weighs five hundred (500) grams or more, or in the absence of weight, is of twenty-two (22) completed weeks of gestation or more. The report shall be in a form or format approved by the State Registrar and shall be submitted to the department's Office of Vital Records within ten (10) days of the delivery.

(Rule 1200-8-1-.11, continued)

(5) Hospitals shall submit their Joint Annual Report data within one hundred and fifty (150) days after the end of each hospital's fiscal year and within one hundred and five (105) days after closure or a change in ownership. Hospitals shall also submit to the department, at the same time the hospital sends the signed paper copy of the report, a notarized statement from the hospital's chief financial officer stating that the financial data reported on the Joint Annual Report is consistent with the audited financials for the hospital for that reporting year. The notarized statement shall also be attested to by the chief executive officer of the submitting hospital.

(6) Hospitals that fail to file their joint annual report timely or that file a joint annual report that does not include all of the required data elements or includes data that does not pass the department's edits shall receive a deficiency from the department. Within ten (10) calendar days, the hospital shall be required to return a plan of correction indicating: how the deficiency will be corrected; the date upon which each deficiency will be corrected; what measures or systemic changes will be put in place to ensure that the deficient practice does not recur; and how the corrective action will be monitored to ensure the deficient practice does not recur. Either failure to submit a plan of correction in a timely manner or a finding by the department that the plan of correction is unacceptable shall subject the hospital's license to possible disciplinary action.

(7) The hospital shall report each case of communicable disease to the local county health officer in the manner provided by existing regulations. Repeated failure to report communicable diseases shall be cause for a revocation of a hospital license.

(8) Unusual events shall be reported by the facility to the Department of Health in a format designed by the Department within seven (7) business days of the date of the identification of the abuse of a patient or an unexpected occurrence or accident that results in death, life threatening or serious injury to a patient.

(a) The following represent circumstances that could result in an unusual event that is an unexpected occurrence or accident resulting in death, life threatening or serious injury to a patient, not related to a natural course of the patient's illness or underlying condition. The circumstances that could result in an unusual event include, but are not limited to:

1. medication errors;

2. aspiration in a non-intubated patient related to conscious/moderate sedation;

3. intravascular catheter related events including necrosis or infection requiring repair or intravascular catheter related pneumothorax;

4. volume overload leading to pulmonary edema;

5. blood transfusion reactions, use of wrong type of blood and/or delivery of blood to the wrong patient;

6. perioperative/periprocedural related complication(s) that occur within 48 hours of the operation or the procedure, including a procedure which results in any new central neurological deficit or any new peripheral neurological deficit with motor weakness;

7. burns of a second or third degree;

8. falls resulting in radiologically proven fractures, subdural or epidural hematoma, cerebral contusion, traumatic subarachnoid hemorrhage, and/or internal trauma, but does not include fractures resulting from pathological conditions;

(Rule 1200-8-1-.11, continued)

9. procedure related incidents, regardless of setting and within thirty (30) days of the procedure and includes readmissions, which include:

(i) procedure related injury requiring repair or removal of an organ;

(ii) hemorrhage;

(iii) displacement, migration or breakage of an implant, device, graft or drain;

(iv) post operative wound infection following clean or clean/contaminated case;

(v) any unexpected operation or reoperation related to the primary procedure;

(vi) hysterectomy in a pregnant woman;

(vii) ruptured uterus;

(viii) circumcision;

(ix) incorrect procedure or incorrect treatment that is invasive;

(x) wrong patient/wrong site surgical procedure;

(xi) unintentionally retained foreign body;

(xii) loss of limb or organ, or impairment of limb if the impairment is present at discharge or for at least two (2) weeks after occurrence;

(xiii) criminal acts;

(xiv) suicide or attempted suicide;

(xv) elopement from the facility;

(xvi) infant abduction, or infant discharged to the wrong family;

(xvii) adult abduction;

(xviii) rape;

(xix) patient altercation;

(xx) patient abuse, patient neglect, or misappropriation of resident/patient funds;

(xxi) restraint related incidents; or

(xxii) poisoning occurring within the facility.

(b) Specific incidents that might result in a disruption of the delivery of health care services at the facility shall also be reported to the department, on the unusual event form, within seven (7) days after the facility learns of the incident. These specific incidents include the following:

1. strike by the staff at the facility;

2. external disaster impacting the facility;

(Rule 1200-8-1-.11, continued)

3. disruption of any service vital to the continued safe operation of the facility or to the health and safety of its patients and personnel; and

4. fires at the facility which disrupt the provision of patient care services or cause harm to patients or staff, or which are reported by the facility to any entity, including but not limited to a fire department, charged with preventing fires.

(c) For health services provided in a "home" setting, only those unusual events actually witnessed or known by the person delivering health care services are required to be reported.

(d) Within forty (40) days of the identification of the event, the facility shall file with the department a corrective action report for the unusual event reported to the department. The department's approval of a Corrective Action Report will take into consideration whether the facility utilized an analysis in identifying the most basic or causal factor(s) that underlie variation in performance leading to the unusual event by (a) determining the proximate cause of the unusual event, (b) analyzing the systems and processes involved in the unusual event, (c) identifying possible common causes, (d) identifying potential improvements, and (e) identifying measures of effectiveness. The corrective action report shall either: (1) explain why a corrective action report is not necessary; or (2) detail the actions taken to correct any error identified that contributed to the unusual event or incident, the date the corrections were implemented, how the facility will prevent the error from recurring in the future and who will monitor the implementation of the corrective action plan.

(e) The department shall approve in writing, the corrective action report if the department is satisfied that the corrective action plan appropriately addresses errors that contributed to the unusual event and takes the necessary steps to prevent the recurrence of the errors. If the department fails to approve the corrective action report, then the department shall provide the facility with a list of actions that the department believes are necessary to address the errors. The facility shall be offered an informal meeting with the Commissioner or the Commissioner's representative to attempt to resolve any disagreement over the corrective action report. If the department and the facility fail to agree on an appropriate corrective action plan, then the final determination on the adequacy of the corrective action report shall be made by the Board after a contested case hearing.

(f) The event report reviewed or obtained by the department shall be confidential and not subject to discovery, subpoena or legal compulsion for release to any person or entity, nor shall the report be admissible in any civil or administrative proceeding other than a disciplinary proceeding by the department or the appropriate regulatory board. The report is not discoverable or admissible in any civil or administrative action except that information in any such report may be transmitted to an appropriate regulatory agency having jurisdiction for disciplinary or license sanctions against the impacted facility. The department must reveal upon request its awareness that a specific event or incident has been reported.

(g) The department shall have access to facility records as allowed in Title 68, Chapter 11, Part 3. The department may copy any portion of a facility medical record relating to the reported event unless otherwise prohibited by rule or statute. This section does not change or affect the privilege and confidentiality provided by T.C.A. §63-6-219.

(h) The department, in developing the unusual event report form, shall establish an event occurrence code that categorizes events or specific incidents by the examples set forth above in (a) and (b). If an event or specific incident fails to come within these examples, it shall be classified as "other" with the facility explaining the facts related to the event or incident.

(Rule 1200-8-1-.11, continued)

(i) This does not preclude the department from using information obtained under these rules in a disciplinary action commenced against a facility, or from taking a disciplinary action against a facility. Nor does this preclude the department from sharing such information with any appropriate governmental agency charged by federal or state law with regulatory oversight of the facility. However, all such information must at all times be maintained as confidential and not available to the public. Failure to report an unusual event, submit a corrective action report, or comply with a plan of correction as required herein may be grounds for disciplinary action pursuant to T.C.A. §68-11-207.

(j) The affected patient and/or the patient's family, as may be appropriate, shall also be notified of the event or incident by the facility.

(k) During the second quarter of each year, the Department shall provide the Board an aggregate report summarizing by type the number of unusual events and incidents reported by facilities to the Department for the preceding calendar year.

(l) The Department shall work with representatives of facilities subject to these rules, and other interested parties, to develop recommendations to improve the collection and assimilation of specific aggregate health care data that, if known, would track health care trends over time and identify system-wide problems for broader quality improvement. The goal of such recommendations should be to better coordinate the collection of such data, to analyze the data, to identify potential problems and to work with facilities to develop best practices to remedy identified problems. The Department shall prepare and issue a report regarding such recommendations.

(9) The hospital shall report information contained in the medical records of patients who have cancer or pre-cancerous or tumorous diseases as provided by existing regulations. These reports shall be sent to the Cancer Reporting System of the department on a quarterly schedule no later than six (6) months after the date of the diagnosis or treatment.

(10) The hospital shall report, at least quarterly to the department, claims data on the UB-92 form or its successor for all discharges from the facility.

(11) The hospital shall report to the department information regarding treatment of traumatic brain injuries. The report must be submitted on a form provided by the department and must include the following information:

(a) Name, age, and residence of the injured person; and

(b) Other information as requested by the department which is currently available and collected by computer in the medical records department of the treating hospital.

(12) The hospital shall retain legible copies of the following records and reports in the facility in a single file for thirty-six (36) months following their issuance and shall be made available for inspection during normal business hours to any patient who requests to view them:

(a) Local fire safety inspections;

(b) Local building code inspections, if any;

(c) Fire marshal reports;

(d) Department licensure and fire safety inspections and surveys;

(Rule 1200-8-1-.11, continued)

(e) Department quality assurance surveys, including follow-up visits, and certification inspections, if any;

(f) Federal Health Care Financing Administration surveys and inspections, if any;

(g) Orders of the Commissioner or Board, if any;

(h) Comptroller of the Treasury's audit reports and finding, if any; and

(i) Maintenance records of all safety equipment.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-207, 68-11-209, 68-11-210, 68-11-211, 68-11-213, and 68-11-310.* ***Administrative History:*** *Original rule filed March 18, 2000; effective May 30, 2000. Amendment filed April 11, 2003; effective June 25, 2003. Amendment filed May 24, 2004; effective August 7, 2004. Amendment filed September 6, 2005; effective November 20, 2005. Amendment filed February 23, 2007; effective May 9, 2007.*

1200-8-1-.12 PATIENT RIGHTS.

(1) Each patient has at least the following rights:

(a) To privacy in treatment and personal care;

(b) To be free from mental and physical abuse. Should this right be violated, the facility must notify the Department within five (5) working days. The Tennessee Department of Human Services, Adult Protection Services shall be notified immediately as required in T.C.A. §71-6-103;

(c) To refuse treatment. The patient must be informed of the consequences of that decision, the refusal and its reason must be reported to the physician and documented in the medical record;

(d) To refuse experimental treatment and drugs. The patient's or health care decision maker's written consent for participation in research must be obtained and retained in his or her medical record;

(e) To have their records kept confidential and private. Written consent by the patient must be obtained prior to release of information except to persons authorized by law. If the patient lacks capacity, written consent is required from the patient's health care decision maker. The hospital must have policies to govern access and duplication of the patient's record;

(f) To have access to a phone number to call if there are questions or complaints about care;

(g) To have appropriate assessment and management of pain; and

(h) To be involved in the decision making of all aspects of their care.

(2) Each patient has a right to self-determination, which encompasses the right to make choices regarding life-sustaining treatment (including resuscitative services). This right of self-determination may be effectuated by an advance directive.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.* ***Administrative History:*** *Original rule filed March 18, 2000; effective May 30, 2000. Amendment filed June 18, 2002; effective September 1, 2002. Amendments filed September 6, 2005; effective November 20, 2005.*

1200-8-1-.13 POLICIES AND PROCEDURES FOR HEALTH CARE DECISION-MAKING.

(Rule 1200-8-1-.13, continued)

(1) Pursuant to this Rule, each hospital shall maintain and establish policies and procedures governing the designation of a health care decision-maker for making health care decisions for a patient who is incompetent or who lacks capacity, including but not limited to allowing the withholding of CPR measures from individual patients. An adult or emancipated minor may give an individual instruction. The instruction may be oral or written. The instruction may be limited to take effect only if a specified condition arises.

(2) An adult or emancipated minor may execute an advance directive for health care. The advance directive may authorize an agent to make any health care decision the patient could have made while having capacity, or may limit the power of the agent, and may include individual instructions. The effect of an advance directive that makes no limitation on the agent's authority shall be to authorize the agent to make any health care decision the patient could have made while having capacity.

(3) The advance directive shall be in writing, signed by the patient, and shall either be notarized or witnessed by two (2) witnesses. Both witnesses shall be competent adults, and neither of them may be the agent. At least one (1) of the witnesses shall be a person who is not related to the patient by blood, marriage, or adoption and would not be entitled to any portion of the estate of the patient upon the death of the patient. The advance directive shall contain a clause that attests that the witnesses comply with the requirements of this paragraph.

(4) Unless otherwise specified in an advance directive, the authority of an agent becomes effective only upon a determination that the patient lacks capacity, and ceases to be effective upon a determination that the patient has recovered capacity.

(5) A facility shall use the mandatory advance directive form that meets the requirements of the Tennessee Health Care Decisions Act and has been developed and issued by the Board for Licensing Health Care Facilities.

(6) A determination that a patient lacks or has recovered capacity, or that another condition exists that affects an individual instruction or the authority of an agent shall be made by the designated physician, who is authorized to consult with such other persons as he or she may deem appropriate.

(7) An agent shall make a health care decision in accordance with the patient's individual instructions, if any, and other wishes to the extent known to the agent. Otherwise, the agent shall make the decision in accordance with the patient's best interest. In determining the patient's best interest, the agent shall consider the patient's personal values to the extent known.

(8) An advance directive may include the individual's nomination of a court-appointed guardian.

(9) A health care facility shall honor an advance directive that is executed outside of this state by a nonresident of this state at the time of execution if that advance directive is in compliance with the laws of Tennessee or the state of the patient's residence.

(10) No health care provider or institution shall require the execution or revocation of an advance directive as a condition for being insured for, or receiving, health care.

(11) Any living will, durable power of attorney for health care, or other instrument signed by the individual, complying with the terms of Tennessee Code Annotated, Title 32, Chapter 11, and a durable power of attorney for health care complying with the terms of Tennessee Code Annotated, Title 34, Chapter 6, Part 2, shall be given effect and interpreted in accord with those respective acts. Any advance directive that does not evidence an intent to be given effect under those acts but that complies with these regulations may be treated as an advance directive under these regulations.

(Rule 1200-8-1-.13, continued)

(12) A patient having capacity may revoke the designation of an agent only by a signed writing or by personally informing the supervising health care provider.

(13) A patient having capacity may revoke all or part of an advance directive, other than the designation of an agent, at any time and in any manner that communicates an intent to revoke.

(14) A decree of annulment, divorce, dissolution of marriage, or legal separation revokes a previous designation of a spouse as an agent unless otherwise specified in the decree or in an advance directive.

(15) An advance directive that conflicts with an earlier advance directive revokes the earlier directive to the extent of the conflict.

(16) Surrogates.

(a) An adult or emancipated minor may designate any individual to act as surrogate by personally informing the supervising health care provider. The designation may be oral or written.

(b) A surrogate may make a health care decision for a patient who is an adult or emancipated minor if and only if:

1. the patient has been determined by the designated physician to lack capacity, and

2. no agent or guardian has been appointed, or

3. the agent or guardian is not reasonably available.

(c) In the case of a patient who lacks capacity, the patient's surrogate shall be identified by the supervising health care provider and documented in the current clinical record of the facility at which the patient is receiving health care.

(d) The patient's surrogate shall be an adult who has exhibited special care and concern for the patient, who is familiar with the patient's personal values, who is reasonably available, and who is willing to serve.

(e) Consideration may be, but need not be, given in order of descending preference for service as a surrogate to:

1. the patient's spouse, unless legally separated;

2. the patient's adult child;

3. the patient's parent;

4. the patient's adult sibling;

5. any other adult relative of the patient; or

6. any other adult who satisfies the requirements of 1200-8-1-.13(16)(d).

(f) No person who is the subject of a protective order or other court order that directs that person to avoid contact with the patient shall be eligible to serve as the patient's surrogate.

(g) The following criteria shall be considered in the determination of the person best qualified to serve as the surrogate:

(Rule 1200-8-1-.13, continued)

1. Whether the proposed surrogate reasonably appears to be better able to make decisions either in accordance with the known wishes of the patient or in accordance with the patient's best interests;

2. The proposed surrogate's regular contact with the patient prior to and during the incapacitating illness;

3. The proposed surrogate's demonstrated care and concern;

4. The proposed surrogate's availability to visit the patient during his or her illness; and

5. The proposed surrogate's availability to engage in face-to-face contact with health care providers for the purpose of fully participating in the decision-making process.

(h) If the patient lacks capacity and none of the individuals eligible to act as a surrogate under 1200-8-1-.13(16)(c) thru 1200-8-1-.13(16)(g) is reasonably available, the designated physician may make health care decisions for the patient after the designated physician either:

1. Consults with and obtains the recommendations of a facility's ethics mechanism or standing committee in the facility that evaluates health care issues; or

2. Obtains concurrence from a second physician who is not directly involved in the patient's health care, does not serve in a capacity of decision-making, influence, or responsibility over the designated physician, and is not under the designated physician's decision-making, influence, or responsibility.

(i) In the event of a challenge, there shall be a rebuttable presumption that the selection of the surrogate was valid. Any person who challenges the selection shall have the burden of proving the invalidity of that selection.

(j) A surrogate shall make a health care decision in accordance with the patient's individual instructions, if any, and other wishes to the extent known to the surrogate. Otherwise, the surrogate shall make the decision in accordance with the surrogate's determination of the patient's best interest. In determining the patient's best interest, the surrogate shall consider the patient's personal values to the extent known to the surrogate.

(k) A surrogate who has not been designated by the patient may make all health care decisions for the patient that the patient could make on the patient's own behalf, except that artificial nutrition and hydration may be withheld or withdrawn for a patient upon a decision of the surrogate only when the designated physician and a second independent physician certify in the patient's current clinical records that the provision or continuation of artificial nutrition or hydration is merely prolonging the act of dying and the patient is highly unlikely to regain capacity to make medical decisions.

(l) Except as provided in 1200-8-1-.13(16)(m):

1. Neither the treating health care provider nor an employee of the treating health care provider, nor an operator of a health care institution nor an employee of an operator of a health care institution may be designated as a surrogate; and

2. A health care provider or employee of a health care provider may not act as a surrogate if the health care provider becomes the patient's treating health care provider.

(m) An employee of the treating health care provider or an employee of an operator of a health care institution may be designated as a surrogate if:

(Rule 1200-8-1-.13, continued)

1. the employee so designated is a relative of the patient by blood, marriage, or adoption; and

2. the other requirements of this section are satisfied.

(n) A health care provider may require an individual claiming the right to act as surrogate for a patient to provide written documentation stating facts and circumstances reasonably sufficient to establish the claimed authority.

(17) Guardian.

(a) A guardian shall comply with the patient's individual instructions and may not revoke the patient's advance directive absent a court order to the contrary.

(b) Absent a court order to the contrary, a health care decision of an agent takes precedence over that of a guardian.

(c) A health care provider may require an individual claiming the right to act as guardian for a patient to provide written documentation stating facts and circumstances reasonably sufficient to establish the claimed authority.

(18) A designated physician who makes or is informed of a determination that a patient lacks or has recovered capacity, or that another condition exists which affects an individual instruction or the authority of an agent, guardian, or surrogate, shall promptly record the determination in the patient's current clinical record and communicate the determination to the patient, if possible, and to any person then authorized to make health care decisions for the patient.

(19) Except as provided in 1200-8-1-.13(20) thru 1200-8-1-.13(22), a health care provider or institution providing care to a patient shall:

(a) comply with an individual instruction of the patient and with a reasonable interpretation of that instruction made by a person then authorized to make health care decisions for the patient; and

(b) comply with a health care decision for the patient made by a person then authorized to make health care decisions for the patient to the same extent as if the decision had been made by the patient while having capacity.

(20) A health care provider may decline to comply with an individual instruction or health care decision for reasons of conscience.

(21) A health care institution may decline to comply with an individual instruction or health care decision if the instruction or decision is:

(a) contrary to a policy of the institution which is based on reasons of conscience, and

(b) the policy was timely communicated to the patient or to a person then authorized to make health care decisions for the patient.

(22) A health care provider or institution may decline to comply with an individual instruction or health care decision that requires medically inappropriate health care or health care contrary to generally accepted health care standards applicable to the health care provider or institution.

(23) A health care provider or institution that declines to comply with an individual instruction or health care decision pursuant to 1200-8-1-.13(20) thru 1200-8-1-.13(22) shall:

(Rule 1200-8-1-.13, continued)

(a) promptly so inform the patient, if possible, and any person then authorized to make health care decisions for the patient;

(b) provide continuing care to the patient until a transfer can be effected or until the determination has been made that transfer cannot be effected;

(c) unless the patient or person then authorized to make health care decisions for the patient refuses assistance, immediately make all reasonable efforts to assist in the transfer of the patient to another health care provider or institution that is willing to comply with the instruction or decision; and

(d) if a transfer cannot be effected, the health care provider or institution shall not be compelled to comply.

(24) Unless otherwise specified in an advance directive, a person then authorized to make health care decisions for a patient has the same rights as the patient to request, receive, examine, copy, and consent to the disclosure of medical or any other health care information.

(25) A health care provider or institution acting in good faith and in accordance with generally accepted health care standards applicable to the health care provider or institution is not subject to civil or criminal liability or to discipline for unprofessional conduct for:

(a) complying with a health care decision of a person apparently having authority to make a health care decision for a patient, including a decision to withhold or withdraw health care;

(b) declining to comply with a health care decision of a person based on a belief that the person then lacked authority; or

(c) complying with an advance directive and assuming that the directive was valid when made and had not been revoked or terminated.

(26) An individual acting as an agent or surrogate is not subject to civil or criminal liability or to discipline for unprofessional conduct for health care decisions made in good faith.

(27) A person identifying a surrogate is not subject to civil or criminal liability or to discipline for unprofessional conduct for such identification made in good faith.

(28) A copy of a written advance directive, revocation of an advance directive, or designation or disqualification of a surrogate has the same effect as the original.

(29) The withholding or withdrawal of medical care from a patient in accordance with the provisions of the Tennessee Health Care Decisions Act shall not, for any purpose, constitute a suicide, euthanasia, homicide, mercy killing, or assisted suicide.

(30) Universal Do Not Resuscitate Order (DNR).

(a) The Physicians Order for Scope of Treatment (POST) form, a mandatory form meeting the provisions of the Health Care Decision Act and approved by the Board for Licensing Health Care Facilities, shall be used as the Universal Do Not Resuscitate Order by all facilities. A universal do not resuscitate order (DNR) may be used by a physician for his/her patient with whom he/she has a physician/patient relationship, but only:

1. with the consent of the patient; or

(Rule 1200-8-1-.13, continued)

2. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order, upon the request of and with the consent of the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act; or

3. if the patient is a minor or is otherwise incapable of making an informed decision regarding consent for such an order and the agent, surrogate, or other person authorized to consent on the patient's behalf under the Tennessee Health Care Decisions Act is not reasonably available, the physician determines that the provision of cardiopulmonary resuscitation would be contrary to accepted medical standards.

(b) If the patient is an adult who is capable of making an informed decision, the patient's expression of the desire to be resuscitated in the event of cardiac or respiratory arrest shall revoke a universal do not resuscitate order. If the patient is a minor or is otherwise incapable of making an informed decision, the expression of the desire that the patient be resuscitated by the person authorized to consent on the patient's behalf shall revoke a universal do not resuscitate order.

(c) Universal do not resuscitate orders shall remain valid and in effect until revoked. Qualified emergency medical services personnel, and licensed health care practitioners in any facility, program or organization operated or licensed by the board for licensing health care facilities or by the department of mental health and developmental disabilities or operated, licensed, or owned by another state agency are authorized to follow universal do not resuscitate orders.

(d) Nothing in these rules shall authorize the withholding of other medical interventions, such as intravenous fluids, oxygen, or other therapies deemed necessary to provide comfort care or to alleviate pain.

(e) If a person with a universal do not resuscitate order is transferred from one health care facility to another health care facility, the health care facility initiating the transfer shall communicate the existence of the universal do not resuscitate order to the receiving facility prior to the transfer. The transferring facility shall assure that a copy of the universal do not resuscitate order accompanies the patient in transport to the receiving health care facility. Upon admission, the receiving facility shall make the universal do not resuscitate order a part of the patient's record.

(f) This section shall not prevent, prohibit, or limit a physician from issuing a written order, other than a universal do not resuscitate order, not to resuscitate a patient in the event of cardiac or respiratory arrest in accordance with accepted medical practices.

(g) Valid do not resuscitate orders or emergency medical services do not resuscitate orders issued before July 1, 2004, pursuant to the then-current law, shall remain valid and shall be given effect as provided.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-224, 68-11-1801 through 68-11-1815.* ***Administrative History:*** *Original rule filed March 18, 2000; effective May 30, 2000. Amendment filed April 28, 2003; effective July 12, 2003. Repeal and new rule filed September 6, 2005; effective November 20, 2005. Amendment filed February 7, 2007; effective April 23, 2007.*

1200-8-1-.14 DISASTER PREPAREDNESS.

(1) Emergency Electrical Power.

(a) All hospitals must have one or more on-site electrical generators which are capable of providing emergency electrical power to at least all life sustaining equipment and life sustaining resources

(Rule 1200-8-1-.14, continued)

such as: ventilators; blood banks, biological refrigerators, safety switches for boilers, safety lighting for corridors and stairwells and other essential equipment.

(b) Connections shall be through a switch which shall automatically transfer the circuits to the emergency power source in case of power failure. (It is recognized that some equipment may not sustain automatic transfer and provisions will have to be made to manually change these items from a non-emergency powered outlet to an emergency powered outlet or other power source).

(c) The emergency power system shall have a minimum of twenty four (24) hours of either propane, natural gas, gasoline or diesel fuel. The quantity shall be based on its expected or known connected load consumption during power interruptions. In addition, the hospital shall have a written contract with an area fuel distributor which guarantees first priority service for re-fills during power interruptions.

(d) The emergency power system shall be inspected weekly and exercised and under actual load and operating temperature conditions for at least thirty (30) minutes, once each month. Records shall be maintained for all inspections and tests and kept on file for a minimum of three (3) years.

(2) Physical Facility and Community Emergency Plans.

(a) Physical Facility (Internal Situations).

1. Every hospital shall have a current internal emergency plan, or plans, that provides for fires, bomb threats, severe weather, utility service failures, plus any local high risk situations such as floods, earthquakes, toxic fumes and chemical spills.

2. The plan(s) must include provisions for the relocation of persons within the building and/or either partial or full building evacuation. Plans that provide for the relocation of patients to other health care facilities must have written agreements for emergency transfers. Their agreements may be mutual, i.e. providing for transfers either way.

3. Copies of the plan(s), either complete or outlines, including specific emergency telephone numbers related to that type of disaster, shall be available to all staff. Provisions that have security implications may be omitted from the outline versions. Familiarization information shall be included in employee orientation sessions and more detailed instructions must be included in continuing education programs. Records of orientation and education programs must be maintained for at least three (3) years.

4. Drills of the disaster preparedness plan shall be conducted at least once a year. The risk focus may vary by type of drill. Drills are for the purpose of educating staff, resource determination, testing personal safety provisions and communications with other facilities and community agencies. Records which document and evaluate these drills must be maintained for at least three (3) years.

5. As soon as possible, real situations that result in a response by local authorities must be documented. This includes a critique of the activation of the plan. Actual documented situations that had education and training value may be substituted for a drill.

(b) Community Emergency (Mass Casualty).

1. Every hospital, unless exempted due to its limited scope of clinical services, shall have a plan that provides for the reception and treatment, within its capabilities, of medical emergencies resulting from a disaster within its usual service area. The plan should

(Rule 1200-8-1-.14, continued)

consider the probability of the types of disasters which might occur, both natural and "man-made".

2. The plan must provide for additional staffing, medical supplies, blood and other resources which would probably be needed. The plan must also include for the deferral of elective admission patients and also for the early transfer or discharge of some current patients if it appears that the number of casualties will exceed available staffed beds.

3. Copies of the plan(s), either complete or outlines, including specific emergency telephone numbers related to that type of disaster, shall be available to staff who would be assigned non-routine duties during these types of emergencies. Familiarization information shall be included in employee orientation sessions and more detailed instruction must be included in continuing education programs. Records of orientation and education must be maintained for at least three (3) years.

4. At least one drill shall be conducted each year for the purpose of educating staff, resource determination, and communications with other facilities and community agencies. Records which document and evaluate these drills must be maintained for at least three (3) years.

5. As soon as possible, actual community emergency situations that result in the treatment of more than twenty (20) patients, or fifteen percent (15%) of the licensed bed capacity, whichever is less, must be documented. Actual situations that had education and training value may be substituted for a drill. This includes documented actual plan activation during community emergencies, even if no patients are received.

(c) Emergency Planning with Local Government Authorities.

1. All hospitals shall establish and maintain communications with the county Emergency Management Agency. This includes the provision of the information and procedures that are needed for the local comprehensive emergency plan. The facility shall cooperate, to the extent possible, in area disaster drills and local emergency situations.

2. Each hospital must rehearse both the Physical Facility and Community Emergency plan as required in these regulations, even if the local Emergency Management Agency is unable to participate.

3. A file of documents demonstrating communications and cooperation with the local agency must be maintained.

Authority: *T.C.A. §§4-5-202, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.* ***Administrative History:*** *Original rule filed March 18, 2000; effective May 30, 2000.*

1200-8-1-.15 APPENDIX I

(1) Physician Orders for Scope of Treatment (POST) Form

COPY OF FORM SHALL ACCOMPANY PATIENT WHEN TRANSFERRED OR DISCHARGED	
Physician Orders for Scope of Treatment (POST)	Patient's Last Name
This is a Physician Order Sheet based on the medical conditions and wishes of the person identified at right ("patient"). Any	First Name/Middle Initial

(Rule 1200-8-1-.15, continued)

section not completed indicates full treatment for that section. When need occurs, first follow these orders, then contact physician.	Date of Birth

Section A — Check One Box Only

CARDIOPULMONARY RESUSCITATION (CPR): Patient has no pulse and/or is not breathing.

☐ Resuscitate (CPR) ☐ Do Not Attempt Resuscitate (DNR/no CPR)

When not in cardiopulmonary arrest, follow orders in B, C, and D.

Section B — Check One Box Only

MEDICAL INTERVENTIONS. Patient has pulse and/or is breathing.

☐ Comfort Measures Treat with dignity and respect. Keep clean, warm, and dry. Use medication by any route, positioning, wound care and other measures to relieve pain and suffering. Use oxygen, suction and manual treatment of airway obstruction as needed for comfort. Do not transfer to hospital for life-sustaining treatment. Transfer only if comfort needs cannot be met in current location.

☐ Limited Additional Interventions Includes care described above. Use medical treatment, IV fluids and cardiac monitoring as indicated. Do not use intubation, advanced airway interventions, or mechanical ventilation. Transfer to hospital if indicated. Avoid intensive care.

☐ Full Treatment. Includes care above. Use intubation, advanced airway interventions mechanical ventilation, and cardioversion as indicated. Transfer to hospital if indicated. Include intensive care.

Other Instructions:_____

Section C — Check One Box Only

ANTIBIOTICS – Treatment for new medical conditions:

☐ No Antibiotics

☐ Antibiotics

Other Instructions:_____

Section D — Check One Box Only in Each Column

MEDICALLY ADMINISTERED FLUIDS AND NUTRITION. Oral fluids and nutrition must be offered if medically feasible.

☐ No IV fluids (provide other measures to assure comfort)	☐ No feeding tube
☐ IV fluids for a defined trial period	☐ Feeding tube for a defined trial period
☐ IV fluids long-term if indicated	☐ Feeding tube long-term

Other Instructions:_____

Section E — Must be Completed

Discussed with:	The Basis for These Orders Is: (Must be completed)
☐ Patient/Resident	☐ Patient's preferences
☐ Health care agent	☐ Patient's best interest (patient lacks capacity or preferences unknown)
☐ Court-appointed guardian	☐ Medical indications
☐ Health care surrogate	☐ (Other)_____
☐ Parent of minor	
☐	
Other:_____(Specify)	

Physician Name (Print)	Physician Phone Number	Office Use Only
Physician Signature (Mandatory)	Date	

COPY OF FORM SHALL ACCOMPANY PATIENT WHEN TRANSFERRED OR DISCHARGED

HIPAA PERMITS DISCLOSURE OF POST TO OTHER HEALTH CARE PROFESSIONALS AS NECESSARY		
Signature of Patient, Parent of Minor, or Guardian/Health Care Representative		
Significant thought has been given to life-sustaining treatment. Preferences have been expressed to a physician and/or health care professional(s). This document reflects those treatment preferences. (If signed by surrogate, preferences expressed must reflect patient's wishes as best understood by surrogate.)		
Signature	Name (print)	Relationship (write "self" if patient)

(Rule 1200-8-1-.15, continued)

Contact Information			
Surrogate	Relationship	Phone Number	
Health Care Professional Preparing Form	Preparer Title	Phone Number	Date Prepared

Directions for Health Care Professionals

Completing POST

Must be completed by a health care professional based on patient preferences, patient best interest, and medical indications.

POST must be signed by a physician to be valid. Verbal orders are acceptable with follow-up signature by physician in accordance with facility/community policy.

Photocopies/faxes of signed POST forms are legal and valid.

Using POST

Any incomplete section of POST implies full treatment for that section.

No defibrillator (including AEDs) should be used on a person who has chosen "Do Not Attempt Resuscitation".

Oral fluids and nutrition must always be offered if medically feasible.

When comfort cannot be achieved in the current setting, the person, including someone with "Comfort Measures Only", should be transferred to a setting able to provide comfort (e.g., treatment of a hip fracture).

IV medication to enhance comfort may be appropriate for a person who has chosen "Comfort Measures Only".

Treatment of dehydration is a measure which prolongs life. A person who desires IV fluids should indicate "Limited Interventions" or "Full Treatment".

A person with capacity, or the surrogate of a person without capacity, can request alternative treatment.

Reviewing POST

This POST should be reviewed if:

(1) The patient is transferred from one care setting or care level to another, or
(2) There is a substantial change in the patient's health status, or
(3) The patient's treatment preferences change.

Draw line through sections A through E and write "VOID" in large letters if POST is replaced or becomes invalid.

Approved by Tennessee Department of Health, Board for Licensing Health Care Facilities, February 2, 2005

COPY OF FORM SHALL ACCOMPANY PATIENT WHEN TRANSFERRED OR DISCHARGED

(2) Advance Care Plan Form

ADVANCE CARE PLAN

Instructions: Competent adults and emancipated minors may give advance instructions using this form or any form of their own choosing. To be legally binding, the Advance Care Plan must be signed and either witnessed or notarized.

(Rule 1200-8-1-.15, continued)

I, _____, hereby give these advance instructions on how I want to be treated by my doctors and other health care providers when I can no longer make those treatment decisions myself.

Agent: I want the following person to make health care decisions for me:

Name:_____ Phone #: _____ Relation: _____

Address: _____

Alternate Agent: If the person named above is unable or unwilling to make health care decisions for me, I appoint as alternate:

Name:_____ Phone #: _____ Relation: _____

Address: _____

Quality of Life:

I want my doctors to help me maintain an acceptable quality of life including adequate pain management. A quality of life that is unacceptable to me means when I have any of the following conditions (you can check as many of these items as you want):

☐ Permanent Unconscious Condition: I become totally unaware of people or surroundings with little chance of ever waking up from the coma.

☐ Permanent Confusion: I become unable to remember, understand or make decisions. I do not recognize loved ones or cannot have a clear conversation with them.

☐ Dependent in all Activities of Daily Living: I am no longer able to talk clearly or move by myself. I depend on others for feeding, bathing, dressing and walking. Rehabilitation or any other restorative treatment will not help.

☐ End-Stage Illnesses: I have an illness that has reached its final stages in spite of full treatment. Examples: Widespread cancer that does not respond anymore to treatment; chronic and/or damaged heart and lungs, where oxygen needed most of the time and activities are limited due to the feeling of suffocation.

Treatment:

If my quality of life becomes unacceptable to me and my condition is irreversible (that is, it will not improve), I direct that medically appropriate treatment be provided as follows. Checking "yes" means I WANT the treatment. Checking "no" means I DO NOT want the treatment.

☐ Yes ☐ No	CPR (Cardiopulmonary Resuscitation): To make the heart beat again and restore breathing after it has stopped. Usually this involves electric shock, chest compressions, and breathing assistance.
☐ Yes ☐ No	Life Support/Other Artificial Support: Continuous use of breathing machine, IV fluids, medications, and other equipment that helps the lungs, heart, kidneys and other organs to continue to work.
☐ Yes ☐ No	Treatment of New Conditions: Use of surgery, blood transfusions, or antibiotics that will deal with a new condition but will not help the main illness.
☐ Yes ☐ No	Tube feeding/IV fluids: Use of tubes to deliver food and water to patient's stomach or use of IV fluids into a vein which would include artificially delivered nutrition and hydration.

Other instructions, such as burial arrangements, hospice care, etc.:_____

(Attach additional pages if necessary)

Organ donation (optional): Upon my death, I wish to make the following anatomical gift (please mark one):

(Rule 1200-8-1-.15, continued)

☐ Any organ/tissue ☐ My entire body ☐ Only the following organs/tissues: _____

SIGNATURE

Your signature should either be witnessed by two competent adults or notarized. If witnessed, neither witness should be the person you appointed as your agent, and at least one of the witnesses should be someone who is not related to you or entitled to any part of your estate.

Signature: _____ DATE:_____
(Patient)

Witnesses:

1, I am a competent adult who is not named as the agent. I witnessed the patient's signature on this form.
_____
Signature of witness number 1

2. I am a competent adult who is not named as the agent. I am not related to the patient by blood, marriage, or adoption and I would not be entitled to any portion of the patient's estate upon his or her death under any existing will or codicil or by operation of law. I witnessed the patient's signature on this form.
_____
Signature of witness number 2

This document may be notarized instead of witnessed:

STATE OF TENNESSEE
COUNTY OF_____

I am a Notary Public in and for the State and County named above. The person who signed this instrument is personally known to me (or proved to me on the basis of satisfactory evidence) to be the person who signed as the "patient". The patient personally appeared before me and signed above or acknowledged the signature above as his or her own. I declare under penalty of perjury that the patient appears to be of sound mind and under no duress, fraud, or undue influence.

My commission expires: _____ _____
Signature of Notary Public

WHAT TO DO WITH THIS ADVANCE DIRECTIVE

- Provide a copy to your physician(s)
- Keep a copy in your personal files where it is accessible to others
- Tell your closest relatives and friends what is in the document
- Provide a copy to the person(s) you named as your health care agent

Approved by Tennessee Department of Health, Board for Licensing Health Care Facilities, February 2, 2005
Acknowledgement to Project GRACE for inspiring the development of this form.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-209, 68-11-224, and 68-11-1805.* ***Administrative History:*** *Original rule filed February 16, 2007; effective May 2, 2007.*